

AMERICAN ACADEMY OF PEDIATRICS

Policy of the
American Academy
of Pediatrics

Pediatric Clinical Practice Guidelines & Policies

**A Compendium of Evidence-based
Research for Pediatric Practice**

15th Edition

**Text
and
CD-ROM
all in one!**

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



Pediatric Clinical Practice Guidelines & Policies

.....

A Compendium of Evidence-based Research for Pediatric Practice

15th Edition

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INTRODUCTION TO *PEDIATRIC CLINICAL PRACTICE GUIDELINES & POLICIES: A COMPENDIUM OF EVIDENCE-BASED RESEARCH FOR PEDIATRIC PRACTICE*

Clinical practice guidelines have long provided physicians with evidence-based decision-making tools for managing common pediatric conditions. Policy statements issued and endorsed by the American Academy of Pediatrics (AAP) are developed to provide physicians with a quick reference guide to the AAP position on child health care issues. We have combined these two authoritative resources into one comprehensive manual/CD-ROM resource to provide easy access to important clinical and policy information.

This manual contains

- Clinical practice guidelines from the AAP, plus related recommendation summaries, ICD-9-CM/ICD-10-CM coding information, and AAP patient education handouts
- Technical report summaries
- Clinical practice guidelines endorsed by the AAP, including abstracts where applicable
- Policy statements, clinical reports, and technical reports issued or endorsed through December 2014, including abstracts where applicable
- Full text of all 2014 AAP policy statements, clinical reports, and technical reports

The CD-ROM, which is located on the inside back cover of this manual, builds on content of the manual and includes full text of all AAP

- Clinical practice guidelines
- Policy statements
- Clinical reports
- Technical reports
- Endorsed clinical practice guidelines and policies

For easy reference within this publication, dates when AAP clinical practice guidelines, policy statements, clinical reports, and technical reports first appeared in the AAP journal *Pediatrics* are provided. In 2009, the online version of *Pediatrics* at <http://pediatrics.aappublications.org> became the official journal of record; therefore, date of online publication is given for policies from 2010 to present.

Additional information about AAP policy can be found in a variety of professional publications such as *Care of the Young Athlete*, 2nd Edition

Guidelines for Perinatal Care, 7th Edition

Pediatric Environmental Health, 3rd Edition

Pediatric Nutrition, 7th Edition

Red Book®, 29th Edition, and *Red Book*® Online (www.aapredbook.org)

To order these and other pediatric resources, please call 888/227-1770 or visit shop.aap.org/books/.



All policy statements, clinical reports, and technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time. Please check the American Academy of Pediatrics Web site at www.aap.org for up-to-date reaffirmations, revisions, and retirements.

AMERICAN ACADEMY OF PEDIATRICS

The American Academy of Pediatrics (AAP) and its member pediatricians dedicate their efforts and resources to the health, safety, and well-being of infants, children, adolescents, and young adults. The AAP has approximately 62,000 members in the United States, Canada, and Latin America. Members include pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Core Values. *We believe*

- In the inherent worth of all children; they are our most enduring and vulnerable legacy.
- Children deserve optimal health and the highest quality health care.
- Pediatricians are the best qualified to provide child health care.

The American Academy of Pediatrics is the organization to advance child health and well-being.

Vision. Children have optimal health and well-being and are valued by society. Academy members practice the highest quality health care and experience professional satisfaction and personal well-being.

Mission. The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To accomplish this mission, the Academy shall support the professional needs of its members.

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FOREWORD

To promote the practice of evidence-based medicine, the American Academy of Pediatrics (AAP) provides physicians with evidence-based guidelines for managing common pediatric conditions. The AAP has an established organizational process and methodology for the development of these clinical practice guidelines.

The evidence-based approach to developing clinical practice guidelines requires systematically defining the problem and identifying interventions and health outcomes. Extensive literature reviews and data syntheses provide the basis for guideline recommendations. Clinical practice guidelines also undergo a thorough peer-review process prior to publication and are periodically reviewed to ensure that they are based on the most current data available.

AAP clinical practice guidelines are designed to provide physicians with an analytic framework for evaluating and treating common pediatric conditions and are not intended as an exclusive course of treatment or standard of care. When using AAP clinical practice guidelines, physicians should continue to consider other sources of information as well as variations in individual circumstances. The AAP recognizes circumstances in which there is a lack of definitive data and relies on expert consensus in cases in which data do not exist. AAP clinical practice guidelines allow for flexibility and adaptability at the local level and should not replace sound clinical judgment.

This manual contains clinical practice guidelines, technical reports, and technical report summaries developed and published by the AAP. Full technical reports are available on the companion CD-ROM. Each one contains a summary of data reviewed, results of data analysis, complete evidence tables, and a bibliography of articles included in the review. This manual also contains abstracts and introductions for evidence-based clinical practice guidelines from other organizations that the AAP has endorsed. Clinical practice guidelines will continually be added to this compendium as they are released or updated. We encourage you to look forward to these future guidelines. Additionally, this edition includes the full text of all policy statements, clinical reports, and technical reports published in 2014 by the AAP as well as abstracts of all active AAP and endorsed policy statements and reports. The full text of all endorsed clinical practice guidelines, as well as all active AAP and endorsed policy statements and reports published prior to 2014, is included on the companion CD-ROM.

If you have any questions about current or future clinical practice guidelines, please contact Kymika Okechukwu at the AAP at 800/433-9016, extension 4317. To order copies of patient education resources that accompany each guideline, please call the AAP at 888/227-1770 or visit shop.aap.org/books/.

Wayne H. Franklin, MD, MPH, MMM, FAAP
Chairperson, Council of Quality Improvement and Patient Safety

ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

.....

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See Appendix 2 for more information.



CLINICAL PRACTICE GUIDELINE

ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

SUBCOMMITTEE ON ATTENTION-DEFICIT/HYPERACTIVITY DISORDER, STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT

KEY WORDS

attention-deficit/hyperactivity disorder, children, adolescents, preschool, behavioral therapy, medication

ABBREVIATIONS

AAP—American Academy of Pediatrics

ADHD—attention-deficit/hyperactivity disorder

DSM-PC—*Diagnostic and Statistical Manual for Primary Care*

CDC—Centers for Disease Control and Prevention

FDA—Food and Drug Administration

DSM-IV—*Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*

MTA—Multimodal Therapy of ADHD

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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abstract



FREE

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurobehavioral disorder of childhood and can profoundly affect the academic achievement, well-being, and social interactions of children; the American Academy of Pediatrics first published clinical recommendations for the diagnosis and evaluation of ADHD in children in 2000; recommendations for treatment followed in 2001. *Pediatrics* 2011;128:1007–1022

Summary of key action statements:

1. The primary care clinician should initiate an evaluation for ADHD for any child 4 through 18 years of age who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity (quality of evidence B/strong recommendation).
2. To make a diagnosis of ADHD, the primary care clinician should determine that *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria have been met (including documentation of impairment in more than 1 major setting); information should be obtained primarily from reports from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care. The primary care clinician should also rule out any alternative cause (quality of evidence B/strong recommendation).
3. In the evaluation of a child for ADHD, the primary care clinician should include assessment for other conditions that might coexist with ADHD, including emotional or behavioral (eg, anxiety, depressive, oppositional defiant, and conduct disorders), developmental (eg, learning and language disorders or other neurodevelopmental disorders), and physical (eg, tics, sleep apnea) conditions (quality of evidence B/strong recommendation).
4. The primary care clinician should recognize ADHD as a chronic condition and, therefore, consider children and adolescents with ADHD as children and youth with special health care needs. Management of children and youth with special health care needs should follow the principles of the chronic care model and the medical home (quality of evidence B/strong recommendation).

5. Recommendations for treatment of children and youth with ADHD vary depending on the patient's age:

- a. For *preschool-aged children (4–5 years of age)*, the primary care clinician should prescribe evidence-based parent- and/or teacher-administered behavior therapy as the first line of treatment (quality of evidence A/strong recommendation) and may prescribe methylphenidate if the behavior interventions do not provide significant improvement and there is moderate-to-severe continuing disturbance in the child's function. In areas where evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication at an early age against the harm of delaying diagnosis and treatment (quality of evidence B/recommendation).
- b. For *elementary school-aged children (6–11 years of age)*, the primary care clinician should prescribe US Food and Drug Administration–approved medications for ADHD (quality of evidence A/strong recommendation) and/or evidence-based parent- and/or teacher-administered behavior therapy as treatment for ADHD, preferably both (quality of evidence B/strong recommendation). The evidence is particularly strong for stimulant medications and sufficient but less strong for atomoxetine, extended-release guanfacine, and extended-release clonidine (in that order) (quality of evidence A/strong recommendation). The school environment, program, or placement is a part of any treatment plan.
- c. For *adolescents (12–18 years of age)*, the primary care clinician

should prescribe Food and Drug Administration–approved medications for ADHD with the assent of the adolescent (quality of evidence A/strong recommendation) and may prescribe behavior therapy as treatment for ADHD (quality of evidence C/recommendation), preferably both.

6. The primary care clinician should titrate doses of medication for ADHD to achieve maximum benefit with minimum adverse effects (quality of evidence B/strong recommendation).

INTRODUCTION

This document updates and replaces 2 previously published clinical guidelines from the American Academy of Pediatrics (AAP) on the diagnosis and treatment of attention-deficit/hyperactivity disorder (ADHD) in children: “Clinical Practice Guideline: Diagnosis and Evaluation of the Child With Attention-Deficit/Hyperactivity Disorder” (2000)¹ and “Clinical Practice Guideline: Treatment of the School-aged Child With Attention-Deficit/Hyperactivity Disorder” (2001).² Since these guidelines were published, new information and evidence regarding the diagnosis and treatment of ADHD has become available. Surveys conducted before and after the publication of the previous guidelines have also provided insight into pediatricians' attitudes and practices regarding ADHD. On the basis of an increased understanding regarding ADHD and the challenges it raises for children and families and as a source for clinicians seeking to diagnose and treat children, this guideline pays particular attention to a number of areas.

Expanded Age Range

The previous guidelines addressed diagnosis and treatment of ADHD in chil-

dren 6 through 12 years of age. There is now emerging evidence to expand the age range of the recommendations to include preschool-aged children and adolescents. This guideline addresses the diagnosis and treatment of ADHD in children 4 through 18 years of age, and attention is brought to special circumstances or concerns in particular age groups when appropriate.

Expanded Scope

Behavioral interventions might help families of children with hyperactive/impulsive behaviors that do not meet full diagnostic criteria for ADHD. Guidance regarding the diagnosis of problem-level concerns in children based on the *Diagnostic and Statistical Manual for Primary Care (DSM-PC)*, *Child and Adolescent Version*,³ as well as suggestions for treatment and care of children and families with problem-level concerns, are provided here. The current DSM-PC was published in 1996 and, therefore, is not consistent with intervening changes to *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)*. Although this version of the DSM-PC should not be used as a definitive source for diagnostic codes related to ADHD and comorbid conditions, it certainly may continue to be used as a resource for enriching the understanding of ADHD manifestations. The DSM-PC will be revised when both the DSM-V and ICD-10 are available for use.

A Process of Care for Diagnosis and Treatment

This guideline and process-of-care algorithm (see Supplemental Fig 2 and Supplemental Appendix) recognizes evaluation, diagnosis, and treatment as a continuous process and provides recommendations for both the guideline and the algorithm in this single publication. In addition to the formal recommendations for assessment, diagnosis, and treatment, this guideline

provides a single algorithm to guide the clinical process.

Integration With the Task Force on Mental Health

This guideline fits into the broader mission of the AAP Task Force on Mental Health and its efforts to provide a base from which primary care providers can develop alliances with families, work to prevent mental health conditions and identify them early, and collaborate with mental health clinicians.

The diagnosis and management of ADHD in children and youth has been particularly challenging for primary care clinicians because of the limited payment provided for what requires more time than most of the other conditions they typically address. The procedures recommended in this guideline necessitate spending more time with patients and families, developing a system of contacts with school and other personnel, and providing continuous, coordinated care, all of which is time demanding. In addition, relegating mental health conditions exclusively to mental health clinicians also is not a viable solution for many clinicians, because in many areas access to mental health clinicians to whom they can refer patients is limited. Access in many areas is also limited to psychologists when further assessment of cognitive issues is required and not available through the education system because of restrictions from third-party payers in paying for the evaluations on the basis of them being educational and not health related.

Cultural differences in the diagnosis and treatment of ADHD are an important issue, as they are for all pediatric conditions. Because the diagnosis and treatment of ADHD depends to a great extent on family and teacher perceptions, these issues might be even more prominent an issue for ADHD. Specific cultural issues

are beyond the scope of this guideline but are important to consider.

METHODOLOGY

As with the 2 previously published clinical guidelines, the AAP collaborated with several organizations to develop a working subcommittee that represented a wide range of primary care and subspecialty groups. The subcommittee included primary care pediatricians, developmental-behavioral pediatricians, and representatives from the American Academy of Child and Adolescent Psychiatry, the Child Neurology Society, the Society for Pediatric Psychology, the National Association of School Psychologists, the Society for Developmental and Behavioral Pediatrics, the American Academy of Family Physicians, and Children and Adults With Attention-Deficit/Hyperactivity Disorder (CHADD), as well as an epidemiologist from the Centers for Disease Control and Prevention (CDC).

This group met over a 2-year period, during which it reviewed the changes in practice that have occurred and issues that have been identified since the previous guidelines were published. Delay in completing the process led to further conference calls and extended the years of literature reviewed in order to remain as current as possible. The AAP funded the development of this guideline; potential financial conflicts of the participants were identified and taken into consideration in the deliberations. The guideline will be reviewed and/or revised in 5 years unless new evidence emerges that warrants revision sooner.

The subcommittee developed a series of research questions to direct an extensive evidence-based review in partnership with the CDC and the University of Oklahoma Health Sciences Center. The diagnostic review was conducted by the CDC, and the evidence was evaluated in a combined effort of

the AAP, CDC, and University of Oklahoma Health Sciences Center staff. The treatment-related evidence relied on a recent evidence review by the Agency for Healthcare Research and Quality and was supplemented by evidence identified through the CDC review.

The diagnostic issues were focused on 5 areas:

1. ADHD prevalence—specifically: (a) What percentage of the general US population aged 21 years or younger has ADHD? (b) What percentage of patients presenting at pediatricians' or family physicians' offices in the United States meet diagnostic criteria for ADHD?
2. Co-occurring mental disorders—of people with ADHD, what percentage has 1 or more of the following co-occurring conditions: sleep disorders, learning disabilities, depression, anxiety, conduct disorder, and oppositional defiant disorder?
3. What are the functional impairments of children and youth diagnosed with ADHD? Specifically, in what domains and to what degree do youth with ADHD demonstrate impairments in functional domains, including peer relations, academic performance, adaptive skills, and family functioning?
4. Do behavior rating scales remain the standard of care in assessing the diagnostic criteria for ADHD?
5. What is the prevalence of abnormal findings on selected medical screening tests commonly recommended as standard components of an evaluation of a child with suspected ADHD? How accurate are these tests in the diagnosis of ADHD compared with a reference standard (ie, what are the psychometric properties of these tests)?

The treatment issues were focused on 3 areas:

1. What new information is available

regarding the long-term efficacy and safety of medications approved by the US Food and Drug Administration (FDA) for the treatment of ADHD (stimulants and nonstimulants), and specifically, what information is available about the efficacy and safety of these medications in preschool-aged and adolescent patients?

2. What evidence is available about the long-term efficacy and safety of psychosocial interventions (behavioral modification) for the treatment of ADHD for children, and specifically, what information is available about the efficacy and safety of these interventions in preschool-aged and adolescent patients?
3. Are there any additional therapies that reach the level of consideration as evidence based?

Evidence-Review Process for Diagnosis

A multilevel, systematic approach was taken to identify the literature that built the evidence base for both diagnosis and treatment. To increase the likelihood that relevant articles were included in the final evidence base, the reviewers first conducted a scoping review of the literature by systematically searching literature using relevant key words and then summarized the primary findings of articles that met standard inclusion criteria. The reviewers then created evidence tables that were reviewed by content-area experts who were best able to identify articles that might have been missed through the scoping review. Articles that were missed were reviewed carefully to determine where the abstraction methodology failed, and adjustments to the search strategy were made as required (see technical report to be published). Finally, although published literature reviews did not contribute directly to the evidence

base, the articles included in review articles were cross-referenced with the final evidence tables to ensure that all relevant articles were included in the final evidence tables.

For the scoping review, articles were abstracted in a stratified fashion from 3 article-retrieval systems that provided access to articles in the domains of medicine, psychology, and education: PubMed (www.ncbi.nlm.nih.gov/sites/entrez), PsycINFO (www.apa.org/pubs/databases/psycinfo/index.aspx), and ERIC (www.eric.ed.gov). English-language, peer-reviewed articles published between 1998 and 2009 were queried in the 3 search engines. Key words were selected with the intent of including all possible articles that might have been relevant to 1 or more of the questions of interest (see the technical report to be published). The primary abstraction included the following terms: “attention deficit hyperactivity disorder” or “attention deficit disorder” or “hyperkinesis” and “child.” A second, independent abstraction was conducted to identify articles related to medical screening tests for ADHD. For this abstraction, the same search terms were used as in the previous procedure along with the additional condition term “behavioral problems” to allow for the inclusion of studies of youth that sought to diagnose ADHD by using medical screening tests. Abstractions were conducted in parallel fashion across each of the 3 databases; the results from each abstraction (complete reference, abstract, and key words) were exported and compiled into a common reference database using EndNote 10.0.⁴ References were subsequently and systematically deduplicated by using the software’s deduplication procedure. References for books, chapters, and theses were also deleted from the library. Once a deduplicated library was developed, the semifinal

database of 8267 references was reviewed for inclusion on the basis of inclusion criteria listed in the technical report. Included articles were then pulled in their entirety, the inclusion criteria were reconfirmed, and then the study findings were summarized in evidence tables. The articles included in relevant review articles were revisited to ensure their inclusion in the final evidence base. The evidence tables were then presented to the committee for expert review.

Evidence-Review Process for Treatment

In addition to this systematic review, for treatment we used the review from the Agency for Healthcare Research and Quality (AHRQ) Effective Healthcare Program “Attention Deficit Hyperactivity Disorder: Effectiveness of Treatment in At-Risk Preschoolers; Long-term Effectiveness in All Ages; and Variability in Prevalence, Diagnosis, and Treatment.”⁵ This review addressed a number of key questions for the committee, including the efficacy of medications and behavioral interventions for preschoolers, children, and adolescents. Evidence identified through the systematic evidence review for diagnosis was also used as a secondary data source to supplement the evidence presented in the AHRQ report. The draft practice guidelines were developed by consensus of the committee regarding the evidence. It was decided to create 2 separate components. The guideline recommendations were based on clear characterization of the evidence. The second component is a practice-of-care algorithm (see Supplemental Fig 2) that provides considerably more detail about how to implement the guidelines but is, necessarily, based less on available evidence and more on consensus of the committee members. When data were lacking, particularly in the

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs or diagnostic studies on relevant population	Strong recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong recommendation	

FIGURE 1

Integrating evidence-quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is conducted leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. The evidence is discussed in more detail in a technical report that will follow in a later publication. RCT indicates randomized controlled trial; Rec, recommendation.

process-of-care algorithmic portion of the guidelines, a combination of evidence and expert consensus was used. Action statements labeled “strong recommendation” or “recommendation” were based on high- to moderate-quality scientific evidence and a preponderance of benefit over harm.⁶ Option-level action statements were based on lesser-quality or limited data and expert consensus or high-quality evidence with a balance between benefits and harms. These clinical options are interventions that a reasonable health care provider might or might not wish to implement in his or her practice. The quality of evidence supporting each recommendation and the strength of each recommendation were assessed by the committee member most experienced in epidemiology and graded according to AAP policy (Fig 1).⁶

The guidelines and process-of-care algorithm underwent extensive peer review by committees, sections, councils, and task forces within the AAP; numerous outside organizations; and other individuals identified by the subcommittee. Liaisons to the subcommittee also were invited to distribute the draft to entities within their organizations. The re-

sulting comments were compiled and reviewed by the chairperson, and relevant changes were incorporated into the draft, which was then reviewed by the full committee.

ABOUT THIS GUIDELINE

Key Action Statements

In light of the concerns highlighted previously and informed by the available evidence, the AAP has developed 6 action statements for the evaluation, diagnosis, and treatment of ADHD in children. These action statements provide for consistent and quality care for children and families with concerns about or symptoms that suggest attention disorders or problems.

Context

This guideline is intended to be integrated with the broader algorithms developed as part of the mission of the AAP Task Force on Mental Health.⁷

Implementation: A Process-of-Care Algorithm

The AAP recognizes the challenge of instituting practice changes and adopting new recommendations for care. To address the need, a process-of-care algorithm has been devel-

oped and has been used in the revision of the AAP ADHD toolkit.

Implementation: Preparing the Practice

Full implementation of the action statements described in this guideline and the process-of-care algorithm might require changes in office procedures and/or preparatory efforts to identify community resources. The section titled “Preparing the Practice” in the process-of-care algorithm and further information can be found in the supplement to the Task Force on Mental Health report.⁷ It is important to document all aspects of the diagnostic and treatment procedures in the patients’ records. Use of rating scales for the diagnosis of ADHD and assessment for comorbid conditions and as a method for monitoring treatment as described in the process algorithm (see Supplemental Fig 2), as well as information provided to parents such as management plans, can help facilitate a clinician’s accurate documentation of his or her process.

Note

The AAP acknowledges that some primary care clinicians might not be confident of their ability to successfully diagnose and treat ADHD in a child because of the child’s age, co-existing conditions, or other concerns. At any point at which a clinician feels that he or she is not adequately trained or is uncertain about making a diagnosis or continuing with treatment, a referral to a pediatric or mental health subspecialist should be made. If a diagnosis of ADHD or other condition is made by a subspecialist, the primary care clinician should develop a management strategy with the subspecialist that ensures that the child will continue to receive appropriate care consistent with a medical home model wherein the pediatrician part-

ners with parents so that both health and mental health needs are integrated.

KEY ACTION STATEMENTS FOR THE EVALUATION, DIAGNOSIS, TREATMENT, AND MONITORING OF ADHD IN CHILDREN AND ADOLESCENTS

Action statement 1: The primary care clinician should initiate an evaluation for ADHD for any child 4 through 18 years of age who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity (quality of evidence B/strong recommendation).

Evidence Profile

- **Aggregate evidence quality:** B.
- **Benefits:** In a considerable number of children, ADHD goes undiagnosed. Primary care clinicians' systematic identification of children with these problems will likely decrease the rate of undiagnosed and untreated ADHD in children.
- **Harms/risks/costs:** Children in whom ADHD is inappropriately diagnosed might be labeled inappropriately, or another condition might be missed, and they might receive treatments that will not benefit them.
- **Benefits-harms assessment:** The high prevalence of ADHD and limited mental health resources require primary care pediatricians to play a significant role in the care of their patients with ADHD so that children with this condition receive the appropriate diagnosis and treatment. Treatments available have shown good evidence of efficacy, and lack of treatment results in a risk for impaired outcomes.
- **Value judgments:** The committee considered the requirements for establishing the diagnosis, the prevalence of ADHD, and the efficacy and adverse effects of treatment as well as the long-term outcomes.

- **Role of patient preferences:** Success with treatment depends on patient and family preference, which has to be taken into account.
- **Exclusions:** None.
- **Intentional vagueness:** The limits between what can be handled by a primary care clinician and what should be referred to a subspecialist because of the varying degrees of skills among primary care clinicians.
- **Strength: strong recommendation.**

The basis for this recommendation is essentially unchanged from that in the previous guideline. ADHD is the most common neurobehavioral disorder in children and occurs in approximately 8% of children and youth^{8–10}; the number of children with this condition is far greater than can be managed by the mental health system. There is now increased evidence that appropriate diagnosis can be provided for preschool-aged children¹¹ (4–5 years of age) and for adolescents.¹²

Action statement 2: To make a diagnosis of ADHD, the primary care clinician should determine that *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV-TR)* criteria have been met (including documentation of impairment in more than 1 major setting), and information should be obtained primarily from reports from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care. The primary care clinician should also rule out any alternative cause (quality of evidence B/strong recommendation).

Evidence Profile

- **Aggregate evidence quality:** B.
- **Benefits:** The use of DSM-IV criteria has led to more uniform categorization of the condition across professional disciplines.

- **Harms/risks/costs:** The DSM-IV system does not specifically provide for developmental-level differences and might lead to some misdiagnoses.
- **Benefits-harms assessment:** The benefits far outweigh the harm.
- **Value judgments:** The committee took into consideration the importance of coordination between pediatric and mental health services.
- **Role of patient preferences:** Although there is some stigma associated with mental disorder diagnoses resulting in some families preferring other diagnoses, the need for better clarity in diagnoses was felt to outweigh this preference.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength: strong recommendation.**

As with the findings in the previous guideline, the DSM-IV criteria continue to be the criteria best supported by evidence and consensus. Developed through several iterations by the American Psychiatric Association, the DSM-IV criteria were created through use of consensus and an expanding research foundation.¹³ The DSM-IV system is used by professionals in psychiatry, psychology, health care systems, and primary care. Use of DSM-IV criteria, in addition to having the best evidence to date for criteria for ADHD, also affords the best method for communication across clinicians and is established with third-party payers. The criteria are under review for the development of the DSM-V, but these changes will not be available until at least 1 year after the publication of this current guideline. The diagnostic criteria have not changed since the previous guideline and are presented in Supplemental Table 2. An anticipated change in the DSM-V is increasing the age limit for when ADHD needs to have first presented from 7 to 12 years.¹⁴

Special Circumstances: Preschool-aged Children (4–5 Years Old)

There is evidence that the diagnostic criteria for ADHD can be applied to preschool-aged children; however, the subtypes detailed in the DSM-IV might not be valid for this population.^{15–21} A review of the literature, including the multisite study of the efficacy of methylphenidate in preschool-aged children, revealed that the criteria could appropriately identify children with the condition.¹¹ However, there are added challenges in determining the presence of key symptoms. Preschool-aged children are not likely to have a separate observer if they do not attend a preschool or child care program, and even if they do attend, staff in those programs might be less qualified than certified teachers to provide accurate observations. Here, too, focused checklists can help physicians in the diagnostic evaluation, although only the Conners Comprehensive Behavior Rating Scales and the ADHD Rating Scale IV are DSM-IV–based scales that have been validated in preschool-aged children.²²

When there are concerns about the availability or quality of nonparent observations of a child's behavior, physicians may recommend that parents complete a parent-training program before confirming an ADHD diagnosis for preschool-aged children and consider placement in a qualified preschool program if they have not done so already. Information can be obtained from parents and teachers through the use of validated DSM-IV–based ADHD rating scales. The parent-training program must include helping parents develop age-appropriate developmental expectations and specific management skills for problem behaviors. The clinician may obtain reports from the parenting class instructor about the parents' ability to manage their children, and if the children are

in programs in which they are directly observed, instructors can report information about the core symptoms and function of the child directly. Qualified preschool programs include programs such as Head Start or other public prekindergarten programs. Preschool-aged children who display significant emotional or behavioral concerns might also qualify for Early Childhood Special Education services through their local school districts, and the evaluators for these programs and/or Early Childhood Special Education teachers might be excellent reporters of core symptoms.

Special Circumstances: Adolescents

Obtaining teacher reports for adolescents might be more challenging, because many adolescents will have multiple teachers. Likewise, parents might have less opportunity to observe their adolescent's behaviors than they had when their children were younger. Adolescents' reports of their own behaviors often differ from those of other observers, because they tend to minimize their own problematic behaviors.^{23–25} Adolescents are less likely to exhibit overt hyperactive behavior. Despite the difficulties, clinicians need to try to obtain (with agreement from the adolescent) information from at least 2 teachers as well as information from other sources such as coaches, school guidance counselors, or leaders of community activities in which the adolescent participates. In addition, it is unusual for adolescents with behavioral/attention problems not to have been previously given a diagnosis of ADHD. Therefore, it is important to establish the younger manifestations of the condition that were missed and to strongly consider substance use, depression, and anxiety as alternative or co-occurring diagnoses. Adolescents with ADHD, especially when untreated, are at greater risk of substance abuse.²⁶ In addition, the risks of

mood and anxiety disorders and risky sexual behaviors increase during adolescence.¹²

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Teachers, parents, and child health professionals typically encounter children with behaviors relating to activity level, impulsivity, and inattention who might not fully meet DSM-IV criteria. The DSM-PC³ provides a guide to the more common behaviors seen in pediatrics. The manual describes common variations in behavior as well as more problematic behaviors at levels of less impairment than those specified in the DSM-IV.

The behavioral descriptions of the DSM-PC have not yet been tested in community studies to determine the prevalence or severity of developmental variations and problems in the areas of inattention, hyperactivity, or impulsivity. They do, however, provide guidance to clinicians regarding elements of treatment for children with problems with mild-to-moderate inattention, hyperactivity, or impulsivity. The DSM-PC also considers environmental influences on a child's behavior and provides information on differential diagnosis with a developmental perspective.

Action statement 3: In the evaluation of a child for ADHD, the primary care clinician should include assessment for other conditions that might coexist with ADHD, including emotional or behavioral (eg, anxiety, depressive, oppositional defiant, and conduct disorders), developmental (eg, learning and language disorders or other neurodevelopmental disorders), and physical (eg, tics, sleep apnea) conditions (quality of evidence B/strong recommendation).

Evidence Profile

- **Aggregate evidence quality:** B.
- **Benefits:** Identifying coexisting conditions is important for developing the most appropriate treatment plan.
- **Harms/risks/costs:** The major risk is misdiagnosing the conditions and providing inappropriate care.
- **Benefits-harms assessment:** There is a preponderance of benefit over harm.
- **Value judgments:** The committee members took into consideration the common occurrence of coexisting conditions and the importance of addressing them in making this recommendation.
- **Role of patient preferences:** None.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength: strong recommendation.**

A variety of other behavioral, developmental, and physical conditions can coexist in children who are evaluated for ADHD. These conditions include, but are not limited to, learning problems, language disorder, disruptive behavior, anxiety, mood disorders, tic disorders, seizures, developmental coordination disorder, or sleep disorders.^{23,24,27–38} In some cases, the presence of a coexisting condition will alter the treatment of ADHD. The primary care clinician might benefit from additional support and guidance or might need to refer a child with ADHD and coexisting conditions, such as severe mood or anxiety disorders, to subspecialists for assessment and management. The subspecialists could include child psychiatrists, developmental-behavioral pediatricians, neurodevelopmental disability physicians, child neurologists, or child or school psychologists.

Given the likelihood that another condition exists, primary care clinicians should conduct assessments that determine or at least identify the risk of coexisting conditions. Through its Task Force on Mental

Health, the AAP has developed algorithms and a toolkit³⁹ for assessing and treating (or comanaging) the most common developmental disorders and mental health concerns in children. These resources might be useful in assessing children who are being evaluated for ADHD. Payment for evaluation and treatment must cover the fixed and variable costs of providing the services, as noted in the AAP policy statement “Scope of Health Care Benefits for Children From Birth Through Age 26.”⁴⁰

Special Circumstances: Adolescents

Clinicians should assess adolescent patients with newly diagnosed ADHD for symptoms and signs of substance abuse; when these signs and symptoms are found, evaluation and treatment for addiction should precede treatment for ADHD, if possible, or careful treatment for ADHD can begin if necessary.²⁵

Action statement 4: The primary care clinician should recognize ADHD as a chronic condition and, therefore, consider children and adolescents with ADHD as children and youth with special health care needs. Management of children and youth with special health care needs should follow the principles of the chronic care model and the medical home (quality of evidence B/strong recommendation).

Evidence Profile

- **Aggregate evidence quality:** B.
- **Benefits:** The recommendation describes the coordinated services most appropriate for managing the condition.
- **Harms/risks/costs:** Providing the services might be more costly.
- **Benefits-harms assessment:** There is a preponderance of benefit over harm.
- **Value judgments:** The committee members considered the value of medical

home services when deciding to make this recommendation.

- **Role of patient preferences:** Family preference in how these services are provided is an important consideration.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength: strong recommendation.**

As in the previous guideline, this recommendation is based on the evidence that ADHD continues to cause symptoms and dysfunction in many children who have the condition over long periods of time, even into adulthood, and that the treatments available address symptoms and function but are usually not curative. Although the chronic illness model has not been specifically studied in children and youth with ADHD, it has been effective for other chronic conditions such as asthma,²³ and the medical home model has been accepted as the preferred standard of care.⁴¹ The management process is also helped by encouraging strong family-school partnerships.⁴²

Longitudinal studies have found that, frequently, treatments are not sustained despite the fact that long-term outcomes for children with ADHD indicate that they are at greater risk of significant problems if they discontinue treatment.⁴³ Because a number of parents of children with ADHD also have ADHD, extra support might be necessary to help those parents provide medication on a consistent basis and institute a consistent behavioral program. The medical home and chronic illness approach is provided in the process algorithm (Supplemental Fig 2). An important process in ongoing care is bidirectional communication with teachers and other school and mental health clinicians involved in the child's care as well as with parents and patients.

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Children with inattention or hyperactivity/impulsivity at the problem level (DSM-PC) and their families might also benefit from the same chronic illness and medical home principles.

Action statement 5: Recommendations for treatment of children and youth with ADHD vary depending on the patient's age.

Action statement 5a: For preschool-aged children (4–5 years of age), the primary care clinician should prescribe evidence-based parent- and/or teacher-administered behavior therapy as the first line of treatment (quality of evidence A/strong recommendation) and may prescribe methylphenidate if the behavior interventions do not provide significant improvement and there is moderate-to-severe continuing disturbance in the child's function. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication at an early age against the harm of delaying diagnosis and treatment (quality of evidence B/recommendation).

Evidence Profile

- **Aggregate evidence quality:** A for behavior; B for methylphenidate.
- **Benefits:** Both behavior therapy and methylphenidate have been demonstrated to reduce behaviors associated with ADHD and improve function.
- **Harms/risks/costs:** Both therapies increase the cost of care, and behavior therapy requires a higher level of family involvement, whereas methylphenidate has some potential adverse effects.
- **Benefits-harms assessment:** Given the risks of untreated ADHD, the benefits outweigh the risks.
- **Value judgments:** The committee mem-

bers included the effects of untreated ADHD when deciding to make this recommendation.

- **Role of patient preferences:** Family preference is essential in determining the treatment plan.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength:** strong recommendation.

Action statement 5b: For elementary school-aged children (6–11 years of age), the primary care clinician should prescribe FDA-approved medications for ADHD (quality of evidence A/strong recommendation) and/or evidence-based parent- and/or teacher-administered behavior therapy as treatment for ADHD, preferably both (quality of evidence B/strong recommendation). The evidence is particularly strong for stimulant medications and sufficient but less strong for atomoxetine, extended-release guanfacine, and extended-release clonidine (in that order) (quality of evidence A/strong recommendation). The school environment, program, or placement is a part of any treatment plan.

Evidence Profile

- **Aggregate evidence quality:** A for treatment with FDA-approved medications; B for behavior therapy.
- **Benefits:** Both behavior therapy and FDA-approved medications have been demonstrated to reduce behaviors associated with ADHD and improve function.
- **Harms/risks/costs:** Both therapies increase the cost of care, and behavior therapy requires a higher level of family involvement, whereas FDA-approved medications have some potential adverse effects.
- **Benefits-harms assessment:** Given the risks of untreated ADHD, the benefits outweigh the risks.
- **Value judgments:** The committee members included the effects of untreated

ADHD when deciding to make this recommendation.

- **Role of patient preferences:** Family preference, including patient preference, is essential in determining the treatment plan.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength:** strong recommendation.

Action statement 5c: For adolescents (12–18 years of age), the primary care clinician should prescribe FDA-approved medications for ADHD with the assent of the adolescent (quality of evidence A/strong recommendation) and may prescribe behavior therapy as treatment for ADHD (quality of evidence C/recommendation), preferably both.

Evidence Profile

- **Aggregate evidence quality:** A for medications; C for behavior therapy.
- **Benefits:** Both behavior therapy and FDA-approved medications have been demonstrated to reduce behaviors associated with ADHD and improve function.
- **Harms/risks/costs:** Both therapies increase the cost of care, and behavior therapy requires a higher level of family involvement, whereas FDA-approved medications have some potential adverse effects.
- **Benefits-harms assessment:** Given the risks of untreated ADHD, the benefits outweigh the risks.
- **Value judgments:** The committee members included the effects of untreated ADHD when deciding to make this recommendation.
- **Role of patient preferences:** Family preference, including patient preference, is essential in determining the treatment plan.
- **Exclusions:** None.
- **Intentional vagueness:** None.
- **Strength:** strong recommendation/recommendation.

Medication

Similar to the recommendations from the previous guideline, stimulant medications are highly effective for most children in reducing core symptoms of ADHD.⁴⁴ One selective norepinephrine-reuptake inhibitor (atomoxetine^{45,46}) and 2 selective α_2 -adrenergic agonists (extended-release guanfacine^{47,48} and extended-release clonidine⁴⁹) have also demonstrated efficacy in reducing core symptoms. Because norepinephrine-reuptake inhibitors and α_2 -adrenergic agonists are newer, the evidence base that supports them—although adequate for FDA approval—is considerably smaller than that for stimulants. None of them have been approved for use in preschool-aged children. Compared with stimulant medications that have an effect size [effect size = (treatment mean – control mean)/control SD] of approximately 1.0,⁵⁰ the effects of the nonstimulants are slightly weaker; atomoxetine has an effect size of approximately 0.7, and extended-release guanfacine and extended-release clonidine also have effect sizes of approximately 0.7.

The accompanying process-of-care algorithm provides a list of the currently available FDA-approved medications for ADHD (Supplemental Table 3). Characteristics of each medication are provided to help guide the clinician's choice in prescribing medication.

As was identified in the previous guideline, the most common stimulant adverse effects are appetite loss, abdominal pain, headaches, and sleep disturbance. The results of the Multimodal Therapy of ADHD (MTA) study revealed a more persistent effect of stimulants on decreasing growth velocity than have most previous studies, particularly when children were on higher and more consistently administered doses. The effects diminished by the third year of treatment, but no com-

pensatory rebound effects were found.⁵¹ However, diminished growth was in the range of 1 to 2 cm. An uncommon additional significant adverse effect of stimulants is the occurrence of hallucinations and other psychotic symptoms.⁵² Although concerns have been raised about the rare occurrence of sudden cardiac death among children using stimulant medications,⁵³ sudden death in children on stimulant medication is extremely rare, and evidence is conflicting as to whether stimulant medications increase the risk of sudden death.^{54–56} It is important to expand the history to include specific cardiac symptoms, Wolf-Parkinson-White syndrome, sudden death in the family, hypertrophic cardiomyopathy, and long QT syndrome. Preschool-aged children might experience increased mood lability and dysphoria.⁵⁷ For the nonstimulant atomoxetine, the adverse effects include initial somnolence and gastrointestinal tract symptoms, particularly if the dosage is increased too rapidly; decrease in appetite; increase in suicidal thoughts (less common); and hepatitis (rare). For the nonstimulant α_2 -adrenergic agonists extended-release guanfacine and extended-release clonidine, adverse effects include somnolence and dry mouth.

Only 2 medications have evidence to support their use as adjunctive therapy with stimulant medications sufficient to achieve FDA approval: extended-release guanfacine²⁶ and extended-release clonidine. Other medications have been used in combination off-label, but there is currently only anecdotal evidence for their safety or efficacy, so their use cannot be recommended at this time.

Special Circumstances: Preschool-aged Children

A number of special circumstances support the recommendation to initi-

ate ADHD treatment in preschool-aged children (ages 4–5 years) with behavioral therapy alone first.⁵⁷ These circumstances include:

- The multisite study of methylphenidate⁵⁷ was limited to preschool-aged children who had moderate-to-severe dysfunction.
- The study also found that many children (ages 4–5 years) experience improvements in symptoms with behavior therapy alone, and the overall evidence for behavior therapy in preschool-aged children is strong.
- Behavioral programs for children 4 to 5 years of age typically run in the form of group parent-training programs and, although not always compensated by health insurance, have a lower cost. The process algorithm (see Supplemental pages s15–16) contains criteria for the clinician to use in assessing the quality of the behavioral therapy. In addition, programs such as Head Start and Children and Adults With Attention Deficit Hyperactivity Disorder (CHADD) (www.chadd.org) might provide some behavioral supports.

Many young children with ADHD might still require medication to achieve maximum improvement, and medication is not contraindicated for children 4 through 5 years of age. However, only 1 multisite study has carefully assessed medication use in preschool-aged children. Other considerations in the recommendation about treating children 4 to 5 years of age with stimulant medications include:

- The study was limited to preschool-aged children who had moderate-to-severe dysfunction.
- Research has found that a number of young children (4–5 years of age) experience improvements in symptoms with behavior therapy alone.
- There are concerns about the possi-

ble effects on growth during this rapid growth period of preschool-aged children.

- There has been limited information about and experience with the effects of stimulant medication in children between the ages of 4 and 5 years.

Here, the criteria for enrollment (and, therefore, medication use) included measures of severity that distinguished treated children from the larger group of preschool-aged children with ADHD. Thus, before initiating medications, the physician should assess the severity of the child's ADHD. Given current data, only those preschool-aged children with ADHD who have moderate-to-severe dysfunction should be considered for medication. Criteria for this level of severity, based on the multisite-study results,⁵⁷ are (1) symptoms that have persisted for at least 9 months, (2) dysfunction that is manifested in both the home and other settings such as preschool or child care, and (3) dysfunction that has not responded adequately to behavior therapy. The decision to consider initiating medication at this age depends in part on the clinician's assessment of the estimated developmental impairment, safety risks, or consequences for school or social participation that could ensue if medications are not initiated. It is often helpful to consult with a mental health specialist who has had specific experience with preschool-aged children if possible. Dextroamphetamine is the only medication approved by the FDA for use in children younger than 6 years of age. This approval, however, was based on less stringent criteria in force when the medication was approved rather than on empirical evidence of its safety and efficacy in this age group. Most of the evidence for the safety and efficacy of treating preschool-aged children with stimulant medications has been

from methylphenidate.⁵⁷ Methylphenidate evidence consists of 1 multisite study of 165 children and 10 other smaller single-site studies that included from 11 to 59 children (total of 269 children); 7 of the 10 single-site studies found significant efficacy. It must be noted that although there is moderate evidence that methylphenidate is safe and efficacious in preschool-aged children, its use in this age group remains off-label. Although the use of dextroamphetamine is on-label, the insufficient evidence for its safety and efficacy in this age group does not make it possible to recommend at this time.

If children do not experience adequate symptom improvement with behavior therapy, medication can be prescribed, as described previously. Evidence suggests that the rate of metabolizing stimulant medication is slower in children 4 through 5 years of age, so they should be given a lower dose to start, and the dose can be increased in smaller increments. Maximum doses have not been adequately studied.⁵⁷

Special Circumstances: Adolescents

As noted previously, before beginning medication treatment for adolescents with newly diagnosed ADHD, clinicians should assess these patients for symptoms of substance abuse. When substance use is identified, assessment when off the abusive substances should precede treatment for ADHD (see the Task Force on Mental Health report⁷). Diversion of ADHD medication (use for other than its intended medical purposes) is also a special concern among adolescents⁵⁸; clinicians should monitor symptoms and prescription-refill requests for signs of misuse or diversion of ADHD medication and consider prescribing medications with no abuse potential, such as atomoxetine (Strattera [Eli Lilly Co, Indianapolis, IN]) and

extended-release guanfacine (Intuniv [Shire US Inc, Wayne, PA]) or extended-release clonidine (Kapvay [Shionogi Inc, Florham Park, NJ]) (which are not stimulants) or stimulant medications with less abuse potential, such as lisdexamfetamine (Vyvanse [Shire US Inc]), dermal methylphenidate (Daytrana [Noven Therapeutics, LLC, Miami, FL]), or OROS methylphenidate (Concerta [Janssen Pharmaceuticals, Inc, Titusville, NJ]). Because lisdexamfetamine is dextroamphetamine, which contains an additional lysine molecule, it is only activated after ingestion, when it is metabolized by erythrocyte cells to dexamphetamine. The other preparations make extraction of the stimulant medication more difficult.

Given the inherent risks of driving by adolescents with ADHD, special concern should be taken to provide medication coverage for symptom control while driving. Longer-acting or late-afternoon, short-acting medications might be helpful in this regard.⁵⁹

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Medication is not appropriate for children whose symptoms do not meet DSM-IV criteria for diagnosis of ADHD, although behavior therapy does not require a specific diagnosis, and many of the efficacy studies have included children without specific mental behavioral disorders.

Behavior Therapy

Behavior therapy represents a broad set of specific interventions that have a common goal of modifying the physical and social environment to alter or change behavior. Behavior therapy usually is implemented by training parents in specific techniques that improve their abilities to modify and

TABLE 1 Evidence-Based Behavioral Treatments for ADHD

Intervention Type	Description	Typical Outcome(s)	Median Effect Size ^a
Behavioral parent training (BPT)	Behavior-modification principles provided to parents for implementation in home settings	Improved compliance with parental commands; improved parental understanding of behavioral principles; high levels of parental satisfaction with treatment	0.55
Behavioral classroom management	Behavior-modification principles provided to teachers for implementation in classroom settings	Improved attention to instruction; improved compliance with classroom rules; decreased disruptive behavior; improved work productivity	0.61
Behavioral peer interventions (BPI) ^b	Interventions focused on peer interactions/relationships; these are often group-based interventions provided weekly and include clinic-based social-skills training used either alone or concurrently with behavioral parent training and/or medication	Office-based interventions have produced minimal effects; interventions have been of questionable social validity; some studies of BPI combined with clinic-based BPT found positive effects on parent ratings of ADHD symptoms; no differences on social functioning or parent ratings of social behavior have been revealed	

^a Effect size = (treatment median — control median)/control SD.

^b The effect size for behavioral peer interventions is not reported, because the effect sizes for these studies represent outcomes associated with combined interventions. A lower effect size means that they have less of an effect. The effect sizes found are considered moderate.

Adapted from Pelham W, Fabiano GA. *J Clin Child Adolesc Psychol*. 2008;37(1):184–214.

shape their child's behavior and to improve the child's ability to regulate his or her own behavior. The training involves techniques to more effectively provide rewards when their child demonstrates the desired behavior (eg, positive reinforcement), learn what behaviors can be reduced or eliminated by using planned ignoring as an active strategy (or using praising and ignoring in combination), or provide appropriate consequences or punishments when their child fails to meet the goals (eg, punishment). There is a need to consistently apply rewards and consequences as tasks are achieved and then to gradually increase the expectations for each task as they are mastered to shape behaviors. Although behavior therapy shares a set of principles, individual programs introduce different techniques and strategies to achieve the same ends.

Table 1 lists the major behavioral intervention approaches that have been demonstrated to be evidence based for the management of ADHD in 3 different types of settings. The table is based on 22 studies, each completed between 1997 and 2006.

Evidence for the effectiveness of behavior therapy in children with ADHD is

derived from a variety of studies^{60–62} and an Agency for Healthcare Research and Quality review.⁵ The diversity of interventions and outcome measures makes meta-analysis of the effects of behavior therapy alone or in association with medications challenging. The long-term positive effects of behavior therapy have yet to be determined. Ongoing adherence to a behavior program might be important; therefore, implementing a chronic care model for child health might contribute to the long-term effects.⁶³

Study results have indicated positive effects of behavior therapy when combined with medications. Most studies that compared behavior therapy to stimulants found a much stronger effect on ADHD core symptoms from stimulants than from behavior therapy. The MTA study found that combined treatment (behavior therapy and stimulant medication) was not significantly more efficacious than treatment with medication alone for the core symptoms of ADHD after correction for multiple tests in the primary analysis.⁶⁴ However, a secondary analysis of a combined measure of parent and teacher ratings of ADHD symptoms revealed a significant advantage

for the combination with a small effect size of $d = 0.26$.⁶⁵ However, the same study also found that the combined treatment compared with medication alone did offer greater improvements on academic and conduct measures when ADHD coexisted with anxiety and when children lived in low socioeconomic environments. In addition, parents and teachers of children who were receiving combined therapy were significantly more satisfied with the treatment plan. Finally, the combination of medication management and behavior therapy allowed for the use of lower dosages of stimulants, which possibly reduced the risk of adverse effects.⁶⁶

School Programming and Supports

Behavior therapy programs coordinating efforts at school as well as home might enhance the effects. School programs can provide classroom adaptations, such as preferred seating, modified work assignments, and test modifications (to the location at which it is administered and time allotted for taking the test), as well as behavior plans as part of a 504 Rehabilitation Act Plan or special education Individualized Education Program (IEP) under the "other health impairment" designation as part of the Individuals With

Disability Education Act (IDEA).⁶⁷ It is helpful for clinicians to be aware of the eligibility criteria in their state and school district to advise families of their options. Youths documented to have ADHD can also get permission to take college-readiness tests in an untimed manner by following appropriate documentation guidelines.⁶⁸

The effect of coexisting conditions on ADHD treatment is variable. In some cases, treatment of the ADHD resolves the coexisting condition. For example, treatment of ADHD might resolve oppositional defiant disorder or anxiety.⁶⁸ However, sometimes the co-occurring condition might require treatment that is in addition to the treatment for ADHD. Some coexisting conditions can be treated in the primary care setting, but others will require referral and co-management with a subspecialist.

Action statement 6: Primary care clinicians should titrate doses of medication for ADHD to achieve maximum benefit with minimum adverse effects (quality of evidence B/strong recommendation).

Evidence Profile

- **Aggregate evidence quality:** B.
- **Benefits:** The optimal dose of medication is required to reduce core symptoms to or as close to the levels of children without ADHD.
- **Harms/risks/costs:** Higher levels of medication increase the chances of adverse effects.
- **Benefits-harms assessment:** The importance of adequately treating ADHD outweighs the risk of adverse effects.
- **Value judgments:** The committee members included the effects of untreated ADHD when deciding to make this recommendation.
- **Role of patient preferences:** The families' preferences and comfort need to be taken into consideration in developing a titration plan.
- **Exclusions:** None.

- **Intentional vagueness:** None.

- **Strength: strong recommendation.**

The findings from the MTA study suggested that more than 70% of children and youth with ADHD respond to one of the stimulant medications at an optimal dose when a systematic trial is used.⁶⁵ Children in the MTA who were treated in the community with care as usual from whomever they chose or to whom they had access received lower doses of stimulants with less frequent monitoring and had less optimal results.⁶⁵ Because stimulants might produce positive but suboptimal effects at a low dose in some children and youth, titration to maximum doses that control symptoms without adverse effects is recommended instead of titration strictly on a milligram-per-kilogram basis.

Education of parents is an important component in the chronic illness model to ensure their cooperation in efforts to reach appropriate titration (remembering that the parents themselves might be challenged significantly by ADHD).^{69,70} The primary care clinician should alert parents and children that changing medication dose and occasionally changing a medication might be necessary for optimal medication management, that the process might require a few months to achieve optimal success, and that medication efficacy should be systematically monitored at regular intervals. Because stimulant medication effects are seen immediately, trials of different doses of stimulants can be accomplished in a relatively short time period. Stimulant medications can be effectively titrated on a 3- to 7-day basis.⁶⁵

It is important to note that by the 3-year follow-up of 14-month MTA interventions (optimal medications management, optimal behavioral management, the combination of the 2, or community treatment), all differences among the initial 4

groups were no longer present. After the initial 14-month intervention, the children no longer received the careful monthly monitoring provided by the study and went back to receiving care from their community providers. Their medications and doses varied, and a number of them were no longer taking medication. In children still on medication, the growth deceleration was only seen for the first 2 years and was in the range of 1 to 2 cm.

CONCLUSION

Evidence continues to be fairly clear with regard to the legitimacy of the diagnosis of ADHD and the appropriate diagnostic criteria and procedures required to establish a diagnosis, identify co-occurring conditions, and treat effectively with both behavioral and pharmacologic interventions. However, the steps required to sustain appropriate treatments and achieve successful long-term outcomes still remain a challenge. To provide more detailed information about how the recommendations of this guideline can be accomplished, a more detailed but less strongly evidence-based algorithm is provided as a companion article.

AREAS FOR FUTURE RESEARCH

Some specific research topics pertinent to the diagnosis and treatment of ADHD or developmental variations or problems in children and adolescents in primary care to be explored include:

- identification or development of reliable instruments suitable to use in primary care to assess the nature or degree of functional impairment in children/adolescents with ADHD and monitor improvement over time;
- study of medications and other therapies used clinically but not approved by the FDA for ADHD, such as

electroencephalographic biofeedback;

- determination of the optimal schedule for monitoring children/adolescents with ADHD, including factors for adjusting that schedule according to age, symptom severity, and progress reports;
- evaluation of the effectiveness of various school-based interventions;
- comparisons of medication use and effectiveness in different ages, including both harms and benefits;
- development of methods to involve parents and children/adolescents in their own care and improve adherence to both behavior and medication treatments;
- standardized and documented tools that will help primary care providers in identifying coexisting conditions;
- development and determination of effective electronic and Web-based systems to help gather information to diagnose and monitor children with ADHD;
- improved systems of communication with schools and mental health professionals, as well as other community agencies, to provide effective collaborative care;
- evidence for optimal monitoring by

some aspects of severity, disability, or impairment; and

- long-term outcomes of children first identified with ADHD as preschool-aged children.

SUBCOMMITTEE ON ATTENTION DEFICIT HYPERACTIVITY DISORDER (OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2005–2011)

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Attention-Deficit/Hyperactivity Disorder Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
 - ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents
- ICD-9-CM/ICD-10-CM Coding Quick Reference for ADHD
- Bonus Features
 - ADHD Coding Fact Sheet for Primary Care Physicians
 - Continuum Model for ADHD
- AAP Patient Education Handouts
 - *Understanding ADHD: Information for Parents About Attention-Deficit/Hyperactivity Disorder*
 - *Medicines for ADHD: Questions From Teens Who Have ADHD*
 - *What Is ADHD? Questions From Teens*

Action Statement Summary

ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

Action statement 1

The primary care clinician should initiate an evaluation for ADHD for any child 4 through 18 years of age who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity (quality of evidence B/strong recommendation).

Action statement 2

To make a diagnosis of ADHD, the primary care clinician should determine that *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV-TR)* criteria have been met (including documentation of impairment in more than 1 major setting), and information should be obtained primarily from reports from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care. The primary care clinician should also rule out any alternative cause (quality of evidence B/strong recommendation).

Action statement 3

In the evaluation of a child for ADHD, the primary care clinician should include assessment for other conditions that might coexist with ADHD, including emotional or behavioral (eg, anxiety, depressive, oppositional defiant, and conduct disorders), developmental (eg, learning and language disorders or other neurodevelopmental disorders), and physical (eg, tics, sleep apnea) conditions (quality of evidence B/strong recommendation).

Action statement 4

The primary care clinician should recognize ADHD as a chronic condition and, therefore, consider children and adolescents with ADHD as children and youth with special health care needs. Management of children and youth with special health care needs should follow the principles of the chronic care model and the medical home

(quality of evidence B/strong recommendation).

Action statement 5

Recommendations for treatment of children and youth with ADHD vary depending on the patient's age.

Action statement 5a

For *preschool-aged children (4–5 years of age)*, the primary care clinician should prescribe evidence-based parent and/or teacher-administered behavior therapy as the first line of treatment (quality of evidence A/strong recommendation) and may prescribe methylphenidate if the behavior interventions do not provide significant improvement and there is moderate-to-severe continuing disturbance in the child's function. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication at an early age against the harm of delaying diagnosis and treatment (quality of evidence B/recommendation).

Action statement 5b

For *elementary school-aged children (6–11 years of age)*, the primary care clinician should prescribe FDA-approved medications for ADHD (quality of evidence A/strong recommendation) and/or evidence based parent- and/or teacher-administered behavior therapy as treatment for ADHD, preferably both (quality of evidence B/strong recommendation). The evidence is particularly strong for stimulant medications and sufficient but less strong for atomoxetine, extended-release guanfacine, and extended-release clonidine (in that order) (quality of evidence A/strong recommendation). The school environment, program, or placement is a part of any treatment plan.

Action statement 5c

For *adolescents (12–18 years of age)*, the primary care clinician should prescribe FDA-approved medications for ADHD with the assent of the adolescent (quality of evidence A/strong recommendation) and may prescribe behavior therapy as treatment for ADHD (quality of evidence C/recommendation), preferably both.

Action statement 6

Primary care clinicians should titrate doses of medication for ADHD to achieve maximum benefit with minimum adverse effects (quality of evidence B/strong recommendation).

Coding Quick Reference for ADHD	
<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
314.00 Attention deficit disorder without hyperactivity	F90.0 Attention-deficit hyperactivity disorder, predominantly inattentive type
314.01 Attention deficit disorder with hyperactivity	F90.1 Attention-deficit hyperactivity disorder, predominantly hyperactive type

ADHD Coding Fact Sheet for Primary Care Physicians

Current Procedural Terminology (CPT®) (Procedure) Codes

Initial assessment usually involves a lot of time determining the differential diagnosis, a diagnostic plan, and potential treatment options. Therefore, most pediatricians will report either an office or outpatient evaluation and management (E/M) code using time as the key factor or a consultation code for the initial assessment.

Physician Evaluation and Management Services

- 99201** Office or other outpatient visit, *new*^a patient; self limited or minor problem, 10 min.
- 99202** low to moderate severity problem, 20 min.
- 99203** moderate severity problem, 30 min.
- 99204** moderate to high severity problem, 45 min.
- 99205** high severity problem, 60 min.
- 99211** Office or other outpatient visit, *established* patient; minimal problem, 5 min.
- 99212** self limited or minor problem, 10 min.
- 99213** low to moderate severity problem, 15 min.
- 99214** moderate severity problem, 25 min.
- 99215** moderate to high severity problem, 40 min.
- 99241** Office or other outpatient *consultation*,^{b-d} new or established patient; self-limited or minor problem, 15 min.
- 99242** low severity problem, 30 min.
- 99243** moderate severity problem, 45 min.
- 99244** moderate to high severity problem, 60 min.
- 99245** moderate to high severity problem, 80 min.
- +99354** Prolonged physician services in office or other outpatient setting, with direct patient contact; first hour (*use in conjunction with time-based codes 99201–99215, 99241–99245, 99301–99350, 90837*)
- +99355** each additional 30 min. (*use in conjunction with 99354*)
- Used when a physician provides prolonged services beyond the usual service (ie, beyond the typical time).
 - Time spent does not have to be continuous.
 - Prolonged service of less than 15 minutes beyond the first hour or less than 15 minutes beyond the final 30 minutes is not reported separately.
 - If reporting E/M service based on time and not key factors (history, examination, medical decision-making), the physician must reach the typical time in the highest code in the code set being reported (eg, **99205**, **99215**, **99245**) before face-to-face prolonged services can be reported.

^a A new patient is one who has not received any professional services (face-to-face services) rendered by physicians and other qualified health care professionals who may report E/M services using one or more specific CPT codes from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past 3 years (CPT 2014 Professional Edition, American Medical Association, p 4).

^b Use of these codes (**99241–99245**) requires the following actions:

1. Written or verbal request for consultation is documented in the patient chart.
2. Consultant's opinion as well as any services ordered or performed are documented in the patient chart.
3. Consultant's opinion and any services that are performed are prepared in a written report, which is sent to the requesting physician or other appropriate source.

^c Patients/parents may not initiate a consultation.

^d For more information on consultation code changes for 2010, see www.aap.org/moc/loadsecure.cfm/reimburse/PositiononMedicareConsultationPolicy.doc.

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

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Reporting E/M Services Using "Time"

- When counseling or coordination of care dominates (more than 50%) the physician/patient or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time shall be considered the key or controlling factor to qualify for a particular level of E/M services.
- This includes time spent with parties who have assumed responsibility for the care of the patient or decision-making, whether or not they are family members (eg, foster parents, person acting in loco parentis, legal guardian). The extent of counseling or coordination of care must be documented in the medical record.
- For coding purposes, face-to-face time for these services is defined as only that time that the physician spends face-to-face with the patient or family. This includes the time in which the physician performs such tasks as obtaining a history, performing an examination, and counseling the patient.
- When codes are ranked in sequential typical times (eg, office-based E/M services, consultation codes) and the actual time is between 2 typical times, the code with the typical time closest to the actual time is used.
 - **Example:** A physician sees an established patient in the office to discuss the current attention-deficit/hyperactivity disorder (ADHD) medication the patient was placed on. The total face-to-face time was 22 minutes, of which 15 minutes was spent in counseling the mom and patient. Because more than 50% of the total time was spent in counseling, the physician would report the E/M service based on time. The physician would report **99214** instead of **99213** because the total face-to-face time was closer to **99214** (25 minutes) than **99213** (15 minutes).

ADHD Follow-up During a Routine Preventive Medicine Service

- A good time to follow up with a patient regarding his or her ADHD could be during a preventive medicine service.
- If the follow-up requires little additional work on behalf of the physician, it should be reported under the preventive medicine service rather than as a separate service.
- If the follow-up work requires an additional E/M service in addition to the preventive medicine service, it should be reported as a separate service.
- Chronic conditions should only be reported if they are separately addressed.
- When reporting a preventive medicine service in addition to an office-based E/M service and the services are significant and separately identifiable, modifier **25** will be required on the office-based E/M service.

— **Example:** A 12-year-old established patient presents for his routine preventive medicine service and while he and Mom are there, Mom asks about changing his ADHD medication because of some side effects he is experiencing. The physician completes the routine preventive medicine check and then addresses the mom's concerns in a separate service. The additional E/M service takes 15 minutes, of which the physician spends about 10 minutes in counseling and coordinating care; therefore, the E/M service is reported based on time.

~ Code **99394** and **99213-25** account for both E/M services and link each to the appropriate ICD-9-CM code.

~ Modifier **25** is required on the problem-oriented office visit code (eg, **99213**) when it is significant and separately identifiable from another service.

Physician Non-Face-to-Face Services

- 99339** Care Plan Oversight—Individual physician supervision of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (e.g., legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15–29 minutes
- 99340** 30 minutes or more
- 99358** Prolonged physician services without direct patient contact; first hour
- +99359** each additional 30 min. (+ *designated add-on code, use in conjunction with 99358*)
- 99367** Medical team conference by physician with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more
- 99441** Telephone evaluation and management to patient, parent or guardian not originating from a related E/M service within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion
- 99442** 11–20 minutes of medical discussion
- 99443** 21–30 minutes of medical discussion
- 99444** Online E/M service provided by a physician or other qualified health care professional to an established patient, guardian or health care provider not originating from a related E/M service provided within the previous 7 days, using the internet or similar electronic communications network

Care Management Services

Codes are selected based on the amount of time spent by clinical staff providing care coordination activities. *Current Procedural Terminology* clearly defines what is defined as care coordination activities. In order to report chronic care management codes, you must

1. Provide 24/7 access to physicians or other qualified health care professionals or clinical staff.
2. Use a standardized methodology to identify patients who require chronic complex care coordination services.
3. Have an internal care coordination process/function whereby a patient identified as meeting the requirements for these services starts receiving them in a timely manner.
4. Use a form and format in the medical record that is standardized within the practice.
5. Be able to engage and educate patients and caregivers as well as coordinate care among all service professionals, as appropriate for each patient.

- 99490** Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient
- chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline
- comprehensive care plan established, implemented, revised, or monitored

Chronic care management services are provided when medical and/or psychosocial needs of the patient require establishing, implementing, revising, or monitoring the care plan. If 20 minutes are not met within a calendar month, you do not report chronic care management. Refer to *CPT* for more information.

Psychiatry

- +90785** Interactive complexity (Use in conjunction with codes for diagnostic psychiatric evaluation [90791, 90792], psychotherapy [90832, 90834, 90837], psychotherapy when performed with an evaluation and management service [90833, 90836, 90838, 99201–99255, 99304–99337, 99341–99350], and group psychotherapy [90853])

Psychiatric Diagnostic or Evaluative Interview Procedures

- 90791** Psychiatric diagnostic interview examination evaluation
- 90792** Psychiatric diagnostic evaluation with medical services

Psychotherapy

- 90832** Psychotherapy, 30 min with patient and/or family; with medical E/M (Use in conjunction with 99201–99255, 99304–99337, 99341–99350)
- +90833**
- 90834** Psychotherapy, 45 min with patient and/or family; with medical E/M services (Use in conjunction with 99201–99255, 99304–99337, 99341–99350)
- +90836**
- 90837** Psychotherapy, 60 min with patient and/or family; with medical E/M services (Use in conjunction with 99201–99255, 99304–99337, 99341–99350)
- +90838**
- +90785** Interactive complexity (Use in conjunction with codes for diagnostic psychiatric evaluation [90791, 90792], psychotherapy [90832, 90834, 90837], psychotherapy when performed with an evaluation and management service [90833, 90836, 90838, 99201–99255, 99304–99337, 99341–99350], and group psychotherapy [90853])
- Refers to specific communication factors that complicate the delivery of a psychiatric procedure. Common factors include more difficult communication with discordant or emotional family members and engagement of young and verbally undeveloped or impaired patients. Typical encounters include
 - Patients who have other individuals legally responsible for their care

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

- Patients who request others to be present or involved in their care such as translators, interpreters, or additional family members
- Patients who require the involvement of other third parties such as child welfare agencies, schools, or probation officers

- 90846** Family psychotherapy (without patient present)
90847 Family psychotherapy (conjoint psychotherapy) (with patient present)

Other Psychiatric Services/Procedures

- 90863** Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (Use in conjunction with **90832**, **90834**, **90837**)
- For pharmacologic management with psychotherapy services performed by a physician or other qualified health care professional who may report E/M codes, use the appropriate E/M codes **99201–99255**, **99281–99285**, **99304–99337**, **99341–99350** and the appropriate psychotherapy with E/M service **90833**, **90836**, **90838**.
 - Note code **90862** was deleted.
- 90887** Interpretation or explanation of results of psychiatric, other medical exams, or other accumulated data to family or other responsible persons, or advising them how to assist patient
- 90889** Preparation of reports on patient's psychiatric status, history, treatment, or progress (other than for legal or consultative purposes) for other physicians, agencies, or insurance carriers

Psychological Testing

- 96101** Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI, Rorschach, WAIS), per hour of the *psychologist's or physician's time*, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report
- 96102** Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI, Rorschach, WAIS), with *qualified health care professional* interpretation and report, administered by technician, per hour of technician time, face-to-face
- 96103** Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI, Rorschach, WAIS), administered by a computer, with *qualified health care professional* interpretation and report
- 96110** Developmental screening with scoring and documentation, per standardized instrument (Do not use for ADHD screens or assessments.)
- 96111** Developmental testing (includes assessment of motor, language, social, adaptive and/or cognitive functioning by standardized instruments) with interpretation and report

- 96116** Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), per hour of the psychologist's or physician's time, both face-to-face time with the patient and time interpreting test results and preparing the report
- 96127** Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument

Nonphysician Provider (NPP) Services

- 99366** Medical team conference with interdisciplinary team of health care professionals, face-to-face with patient and/or family, 30 minutes or more, participation by a nonphysician qualified health care professional
- 99368** Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more, participation by a nonphysician qualified health care professional
- 96120** Neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report
- 96150** Health and behavior assessment performed by nonphysician provider (health-focused clinical interviews, behavior observations) to identify psychological, behavioral, emotional, cognitive or social factors important to management of physical health problems, 15 min., initial assessment
- 96151** re-assessment
- 96152** Health and behavior intervention performed by nonphysician provider to improve patient's health and well-being using cognitive, behavioral, social, and/or psychophysiological procedures designed to ameliorate specific disease-related problems, individual, 15 min.
- 96153** group (2 or more patients)
- 96154** family (with the patient present)
- 96155** family (without the patient present)

Non-Face-to-Face Services: NPP

- 98966** Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent or guardian not originating from a related assessment and management service provided within the previous seven days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment;
- 5–10 minutes of medical discussion
 - 11–20 minutes of medical discussion
 - 21–30 minutes of medical discussion
- 98967**
- 98968**
- 98969** Online assessment and management service provided by a qualified nonphysician health care professional to an established patient or guardian not originating from a related assessment and management service provided within the previous seven days nor using the internet or similar electronic communications network

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

Miscellaneous Services

- 99071** Educational supplies, such as books, tapes, or pamphlets, provided by the physician for the patient's education at cost to the physician

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)

- Use as many diagnosis codes that apply to document the patient's complexity and report the patient's symptoms or adverse environmental circumstances.
- Once a definitive diagnosis is established, report the appropriate definitive diagnosis code(s) as the primary code, plus any other symptoms that the patient is exhibiting as secondary diagnoses.
- Counseling diagnosis codes can be used when the patient is present or when counseling the parent(s) or guardian(s) when the patient is not physically present.
- Report ICD-9-CM codes through September 30, 2014.

- 285.9** Anemia, unspecified
292.84 Drug-induced mood disorder (Add E-code to identify the drug)
293.84 Anxiety disorder in conditions classified elsewhere
296.81 Atypical manic disorder
296.90 Unspecified episodic mood disorder
299.00 Autistic disorder, current or active state
299.01 Autistic disorder, residual state
300.00 Anxiety state, unspecified
300.01 Panic disorder
300.02 Generalized anxiety disorder
300.20 Phobia, unspecified
300.23 Social phobia
300.29 Other isolated or specific phobia
300.4 Dysthymic disorder
300.9 Unspecified nonpsychotic mental disorder
304.3 Cannabis dependence
304.4 Amphetamine and other psychostimulant dependence
304.9 Unspecified drug dependence

Substance Dependence/Abuse

For the following codes (**305.0X–305.9X**), fifth-digit subclassification is as follows:

- 0** unspecified
1 continuous
2 episodic
3 in remission

Nondependent Abuse of Drugs

- 305.0X** Alcohol abuse
305.1X Tobacco use disorder
305.2X Cannabis abuse
305.3X Hallucinogenic abuse
305.4X Sedative, hypnotic or anxiolytic abuse
305.5X Opioid abuse
305.6X Cocaine abuse
305.7X Amphetamine or related acting sympathomimetic abuse
305.8X Antidepressant type abuse
305.9X Other mixed, or unspecified drug abuse (eg, caffeine intoxication, laxative habit)
307.0 Stuttering

- 307.20** Tic disorder, unspecified
307.21 Transient tic disorder
307.22 Chronic motor or vocal tic disorder
307.23 Tourette's disorder
307.40 Nonorganic sleep disorder, unspecified
307.41 Transient disorder of initiating or maintaining sleep
307.42 Persistent disorder of initiating or maintaining sleep
307.46 Sleep arousal disorder
307.49 Other sleep disorder
307.50 Eating disorder, unspecified
307.52 Pica
307.6 Enuresis
307.9 Other and unspecified special symptoms or syndromes, not elsewhere classified (NEC)
308.0 Predominant disturbance of emotions
309.0 Adjustment disorder with depressed mood
309.21 Separation anxiety disorder
309.24 Adjustment disorder with anxiety
309.3 Adjustment reaction; with disturbance of conduct
309.9 Unspecified adjustment reaction
310.2 Postconcussion syndrome
310.8 Other specified nonpsychotic mental disorders following organic brain damage
310.9 Unspecified nonpsychotic mental disorders following organic brain damage
312.00 Undersocialized conduct disorder, aggressive type; unspecified
312.30 Impulse control disorder, unspecified
312.81 Conduct disorder, childhood onset type
312.82 Conduct disorder, adolescent onset type
312.9 Unspecified disturbance of conduct
313.3 Relationship problems
313.81 Oppositional defiant disorder
313.83 Academic underachievement disorder
313.9 Unspecified emotional disturbance of childhood or adolescence
314.00 Attention-deficit disorder, without mention of hyperactivity
314.01 Attention-deficit disorder, with mention of hyperactivity
314.1 Hyperkinesis with developmental delay
(Use additional code to identify any associated neurological disorder)
314.2 Hyperkinetic conduct disorder
314.8 Other specified manifestations of hyperkinetic syndrome
314.9 Unspecified hyperkinetic syndrome
315.00 Reading disorder, unspecified
315.01 Alexia
315.02 Developmental dyslexia
315.09 Specific reading disorder; other
315.1 Mathematics disorder
315.2 Specific learning difficulties; other
315.31 Expressive language disorder
315.32 Mixed receptive-expressive language disorder
315.34 Speech and language developmental delay due to hearing loss
315.39 Developmental speech or language disorder; other
315.4 Developmental coordination disorder
315.5 Mixed development disorder
315.8 Specified delays in development; other
315.9 Unspecified delay in development
317 Mild mental retardation

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

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318.0	Moderate mental retardation
318.1	Severe mental retardation
318.2	Profound mental retardation
319	Unspecified mental retardation
389.03	Conductive hearing loss, middle ear
527.7	Disturbance of salivary secretion (eg, dry mouth/xerostomia)
564.00	Constipation, unspecified
780.4	Dizziness
780.50	Sleep disturbances, unspecified
781.0	Abnormal involuntary movement (eg, tremor)
781.3	Lack of coordination
782.1	Rash and other nonspecific skin eruptions
783.1	Abnormal weight gain
783.21	Loss of weight
783.3	Feeding difficulties and mismanagement
783.42	Delayed milestones
783.43	Short stature
784.0	Headache
787.01	Nausea with vomiting
787.03	Vomiting
787.91	Diarrhea
788.36	Nocturnal enuresis
789.00	Abdominal pain, unspecified
984.9	Toxic effect of lead, unspecified lead compound (Use E code in addition)

The following diagnosis codes (**V11.1–V79.9**) are used to deal with occasions when circumstances other than a disease or an injury are recorded as diagnoses or problems. Some carriers may request supporting documentation for the reporting of V codes. These codes may also be reported in addition to the primary ICD-9-CM code to list any contributing factors or those factors that influence the person's health status but are not in themselves a current illness or injury.

V11.1	Personal history of affective disorders
V11.8	Personal history of other mental disorders
V11.9	Personal history of unspecified mental disorders
V12.1	Personal history of a nutritional deficiency
V12.2	Personal history of endocrine, metabolic, and nutritional disorders
V12.3	Personal history of diseases of blood and blood-forming organs
V12.40	Unspecified disorder of the neurological system and sense organs
V12.49	Other disorders of the nervous system and sense organs
V12.69	Other disorders of the respiratory system
V12.79	Other diseases of the digestive system
V13.6	Congenital malformations
V14.9	Personal history of allergy to unspecified medicinal agent
V15.0	Allergy, other than to medicinal agents
V15.41	History of physical abuse
V15.42	History of emotional abuse
V15.49	Other psychological trauma
V15.52	History of traumatic brain injury
V15.81	Noncompliance with medical treatment
V15.82	History of tobacco use
V15.86	Contact with and (suspected) exposure to lead
V17.0	Family history of psychiatric disorder
V18.2	Family history of anemia

V18.4	Family history of mental retardation
V40.0	Problems with learning
V40.1	Problems with communication (including speech)
V40.2	Mental problems; other
V40.3	Behavioral problems; other
V40.9	Mental or behavioral problems; unspecified
V58.69	Long-term (current) use of other medications
V60.0	Lack of housing
V60.1	Inadequate housing
V60.2	Inadequate material resources (eg, economic problem, poverty, NOS)
V60.81	Foster care
V61.20	Counseling for parent-child problem; unspecified
V61.23	Counseling for parent-biological child problem
V61.24	Counseling for parent-adopted child problem
V61.25	Counseling for parent (guardian)-foster child problem
V61.29	Counseling for parent-child problem; other
V61.41	Health problems within family; alcoholism
V61.42	Health problems within family; substance abuse
V61.49	Health problems within family; other
V61.8	Health problems within family; other specified family circumstances
V61.9	Health problems within family; unspecified family circumstances
V62.3	Educational circumstances
V62.4	Social maladjustment
V62.5	Legal circumstances
V62.81	Interpersonal problems, NEC
V62.89	Other psychological or physical stress; NEC, other
V62.9	Other psychosocial circumstance
V65.40	Counseling NOS
V65.49	Other specified counseling
V79.0	Special screening for depression
V79.2	Special screening for mental retardation
V79.3	Special screening for developmental handicaps in early childhood
V79.8	Special screening for other specified mental disorders and developmental handicaps
V79.9	Unspecified mental disorder and developmental handicapped

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Codes

- Use as many diagnosis codes that apply to document the patient's complexity and report the patient's symptoms and/or adverse environmental circumstances.
- Once a definitive diagnosis is established, report the appropriate definitive diagnosis code(s) as the primary code, plus any other symptoms that the patient is exhibiting as secondary diagnoses that are not part of the usual disease course or are considered incidental.
- **ICD-10-CM codes are only valid on or after October 1, 2015.**

Depressive Disorders

F34.1	Dysthymic disorder (depressive personality disorder, dysthymia neurotic depression)
F39	Mood (affective) disorder, unspecified
F30.8	Other manic episode

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

Anxiety Disorders

- F06.4** Anxiety disorder due to known physiological conditions
- F40.10** Social phobia, unspecified
- F40.11** Social phobia, generalized
- F40.8** Phobic anxiety disorders, other (phobic anxiety disorder of childhood)
- F40.9** Phobic anxiety disorder, unspecified
- F41.1** Generalized anxiety disorder
- F41.9** Anxiety disorder, unspecified

Feeding and Eating Disorders/Elimination Disorders

- F50.8** Eating disorders, other
- F50.9** Eating disorder, unspecified
- F98.0** Enuresis not due to a substance or known physiological condition
- F98.1** Encopresis not due to a substance or known physiological condition
- F98.3** Pica (infancy or childhood)

Impulse Disorders

- F63.9** Impulse disorder, unspecified

Trauma- and Stressor-Related Disorders

- F43.20** Adjustment disorder, unspecified
- F43.21** Adjustment disorder with depressed mood
- F43.22** Adjustment disorder with anxiety
- F43.23** Adjustment disorder with mixed anxiety and depressed mood
- F43.24** Adjustment disorder with disturbance of conduct

Neurodevelopmental/Other Developmental Disorders

- F70** Mild intellectual disabilities
- F71** Moderate intellectual disabilities
- F72** Severe intellectual disabilities
- F73** Profound intellectual disabilities
- F79** Unspecified intellectual disabilities
- F80.0** Phonological (speech) disorder
- F80.1** Expressive language disorder
- F80.2** Mixed receptive-expressive language disorder
- F80.4** Speech and language developmental delay due to hearing loss (code also hearing loss)
- F80.81** Stuttering
- F80.89** Other developmental disorders of speech and language
- F80.9** Developmental disorder of speech and language, unspecified
- F81.0** Specific reading disorder
- F81.2** Mathematics disorder
- F81.89** Other developmental disorders of scholastic skills
- F82** Developmental coordination disorder
- F88** Specified delays in development; other
- F89** Unspecified delay in development
- F81.9** Developmental disorder of scholastic skills, unspecified

Behavioral/Emotional Disorders

- F90.0** Attention-deficit hyperactivity disorder, predominantly inattentive type
- F90.1** Attention-deficit hyperactivity disorder, predominantly hyperactive type

- F90.8** Attention-deficit hyperactivity disorder, other type
- F90.9** Attention-deficit hyperactivity disorder, unspecified type
- F91.1** Conduct disorder, childhood-onset type
- F91.2** Conduct disorder, adolescent-onset type
- F91.3** Oppositional defiant disorder
- F91.9** Conduct disorder, unspecified
- F93.0** Separation anxiety disorder
- F93.8** Other childhood emotional disorders (relationship problems)
- F93.9** Childhood emotional disorder, unspecified
- F94.9** Childhood disorder of social functioning, unspecified
- F95.0** Transient tic disorder
- F95.1** Chronic motor or vocal tic disorder
- F95.2** Tourette's disorder
- F95.9** Tic disorder, unspecified
- F98.8** Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence (nail-biting, nose-picking, thumb-sucking)

Other

- F07.81** Postconcussional syndrome
- F07.89** Personality and behavioral disorders due to known physiological condition, other
- F07.9** Personality and behavioral disorder due to known physiological condition, unspecified
- F48.8** Nonpsychotic mental disorders, other (neurasthenia)
- F48.9** Nonpsychotic mental disorders, unspecified
- F45.41** Pain disorder exclusively related to psychological factors
- F51.01** Primary insomnia
- F51.02** Adjustment insomnia
- F51.03** Paradoxical insomnia
- F51.04** Psychophysiological insomnia
- F51.05** Insomnia due to other mental disorder (Code also associated mental disorder)
- F51.09** Insomnia, other (not due to a substance or known physiological condition)
- F51.3** Sleepwalking [somnambulism]
- F51.4** Sleep terrors [night terrors]
- F51.8** Other sleep disorders
- F93.8** Childhood emotional disorders, other
- R46.89** Other symptoms and signs involving appearance and behavior

Substance-Related and Addictive Disorders

If a provider documents multiple patterns of use, only one should be reported. Use the following hierarchy: use–abuse–dependence (eg, if use and dependence are documented, only code for dependence).

When a minus symbol (-) is included in codes **F10–F17**, a last character is required. Be sure to include the last character from the following list:

- 0** anxiety disorder
- 2** sleep disorder
- 8** other disorder
- 9** unspecified disorder

Alcohol

- F10.10** Alcohol abuse, uncomplicated
- F10.14** Alcohol abuse with alcohol-induced mood disorder

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

- F10.159** Alcohol abuse with alcohol-induced psychotic disorder, unspecified
- F10.18-** Alcohol abuse with alcohol-induced
- F10.19** Alcohol abuse with unspecified alcohol-induced disorder
- F10.20** Alcohol dependence, uncomplicated
- F10.21** Alcohol dependence, in remission
- F10.24** Alcohol dependence with alcohol-induced mood disorder
- F10.259** Alcohol dependence with alcohol-induced psychotic disorder, unspecified
- F10.28-** Alcohol dependence with alcohol-induced
- F10.29** Alcohol dependence with unspecified alcohol-induced disorder
- F10.94** Alcohol use, unspecified with alcohol-induced mood disorder
- F10.959** Alcohol use, unspecified with alcohol-induced psychotic disorder, unspecified
- F10.98-** Alcohol use, unspecified with alcohol-induced
- F10.99** Alcohol use, unspecified with unspecified alcohol-induced disorder

Cannabis

- F12.10** Cannabis abuse, uncomplicated
- F12.18-** Cannabis abuse with cannabis-induced
- F12.19** Cannabis abuse with unspecified cannabis-induced disorder
- F12.20** Cannabis dependence, uncomplicated
- F12.21** Cannabis dependence, in remission
- F12.28-** Cannabis dependence with cannabis-induced
- F12.29** Cannabis dependence with unspecified cannabis-induced disorder
- F12.90** Cannabis use, unspecified, uncomplicated
- F12.98-** Cannabis use, unspecified with
- F12.99** Cannabis use, unspecified with unspecified cannabis-induced disorder

Sedatives

- F13.10** Sedative, hypnotic or anxiolytic abuse, uncomplicated
- F13.129** Sedative, hypnotic or anxiolytic abuse with intoxication, unspecified
- F13.14** Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced mood disorder
- F13.18-** Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced
- F13.21** Sedative, hypnotic or anxiolytic dependence, in remission
- F13.90** Sedative, hypnotic, or anxiolytic use, unspecified, uncomplicated
- F13.94** Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced mood disorder
- F13.98-** Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced
- F13.99** Sedative, hypnotic or anxiolytic use, unspecified with unspecified sedative, hypnotic or anxiolytic-induced disorder

Stimulants (eg, Caffeine, Amphetamines)

- F15.10** Other stimulant (amphetamine-related disorders or caffeine) abuse, uncomplicated
- F15.14** Other stimulant (amphetamine-related disorders or caffeine) abuse with stimulant-induced mood disorder

- F15.18-** Other stimulant (amphetamine-related disorders or caffeine) abuse with stimulant-induced
- F15.19** Other stimulant (amphetamine-related disorders or caffeine) abuse with unspecified stimulant-induced disorder
- F15.20** Other stimulant (amphetamine-related disorders or caffeine) dependence, uncomplicated
- F15.21** Other stimulant (amphetamine-related disorders or caffeine) dependence, in remission
- F15.24** Other stimulant (amphetamine-related disorders or caffeine) dependence with stimulant-induced mood disorder
- F15.28-** Other stimulant (amphetamine-related disorders or caffeine) dependence with stimulant-induced
- F15.29** Other stimulant (amphetamine-related disorders or caffeine) dependence with unspecified stimulant-induced disorder
- F15.90** Other stimulant (amphetamine-related disorders or caffeine) use, unspecified, uncomplicated
- F15.94** Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with stimulant-induced mood disorder
- F15.98-** Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with stimulant-induced
- F15.99** Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with unspecified stimulant-induced disorder

Nicotine (eg, Cigarettes)

- F17.200** Nicotine dependence, unspecified, uncomplicated
- F17.201** Nicotine dependence, unspecified, in remission
- F17.203** Nicotine dependence unspecified, with withdrawal
- F17.20-** Nicotine dependence, unspecified, with
- F17.210** Nicotine dependence, cigarettes, uncomplicated
- F17.211** Nicotine dependence, cigarettes, in remission
- F17.213** Nicotine dependence, cigarettes, with withdrawal
- F17.218-** Nicotine dependence, cigarettes, with

Symptoms, Signs, and Ill-Defined Conditions

- Use these codes in absence of a definitive mental diagnosis or when the sign or symptom is not part of the disease course or considered incidental.

- G47.9** Sleep disorder, unspecified
- H90.0** Conductive hearing loss, bilateral
- H90.11** Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
- H90.12** Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
- K11.7** Disturbance of salivary secretions
- K59.00** Constipation, unspecified
- N39.44** Nocturnal enuresis
- R10.0** Acute abdomen pain
- R11.11** Vomiting without nausea
- R11.2** Nausea with vomiting, unspecified
- R19.7** Diarrhea, unspecified
- R21** Rash, NOS
- R25.0** Abnormal head movements
- R25.1** Tremor, unspecified
- R25.3** Twitching, NOS
- R25.8** Other abnormal involuntary movements
- R25.9** Unspecified abnormal involuntary movements

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

R27.8 Other lack of coordination (excludes ataxia)
R27.9 Unspecified lack of coordination
R41.83 Borderline intellectual functioning
R42 Dizziness
R48.0 Alexia/dyslexia, NOS
R51 Headache
R62.0 Delayed milestone in childhood
R62.52 Short stature (child)
R63.3 Feeding difficulties
R63.4 Abnormal weight loss
R63.5 Abnormal weight gain
R68.2 Dry mouth, unspecified
T56.0X1A Toxic effect of lead and its compounds, accidental (unintentional), initial encounter

Z Codes

Z codes represent reasons for encounters. Categories **Z00–Z99** are provided for occasions when circumstances other than a disease, injury, or external cause classifiable to categories **A00–Y89** are recorded as *diagnoses* or *problems*. This can arise in 2 main ways.

- When a person who may or may not be sick encounters the health services for some specific purpose, such as to receive limited care or service for a current condition, to donate an organ or tissue, to receive prophylactic vaccination (immunization), or to discuss a problem that is in itself not a disease or an injury.
- When some circumstance or problem is present which influences the person's health status but is not in itself a current illness or injury.

Z13.89 Encounter for screening for other disorder
Z55.0 Illiteracy and low-level literacy
Z55.2 Failed school examinations
Z55.3 Underachievement in school
Z55.4 Educational maladjustment and discord with teachers and classmates
Z55.8 Other problems related to education and literacy
Z55.9 Problems related to education and literacy, unspecified (**Z55** codes exclude those conditions reported with **F80–F89**)
Z62.0 Inadequate parental supervision and control
Z60.4 Social exclusion and rejection
Z60.8 Other problems related to social environment
Z60.9 Problem related to social environment, unspecified
Z62.21 Foster care status (child welfare)
Z62.6 Inappropriate (excessive) parental pressure
Z62.810 Personal history of physical and sexual abuse in childhood
Z62.811 Personal history of psychological abuse in childhood

Z62.820 Parent-biological child conflict
Z62.821 Parent-adopted child conflict
Z62.822 Parent-foster child conflict
Z63.72 Alcoholism and drug addiction in family
Z63.8 Other specified problems related to primary support group
Z65.3 Problems related to legal circumstances
Z71.89 Counseling, other specified
Z71.9 Counseling, unspecified
Z72.0 Tobacco use
Z77.011 Contact with and (suspected) exposure to lead
Z79.899 Other long term (current) drug therapy
Z81.0 Family history of intellectual disabilities (conditions classifiable to **F70–F79**)
Z81.8 Family history of other mental and behavioral disorders
Z83.2 Family history of diseases of the blood and blood-forming organs (anemia) (conditions classifiable to **D50–D89**)
Z86.2 Personal history of diseases of the blood and blood-forming organs
Z86.39 Personal history of other endocrine, nutritional, and metabolic disease
Z86.59 Personal history of other mental and behavioral disorders
Z86.69 Personal history of other diseases of the nervous system and sense organs
Z87.09 Personal history of other diseases of the respiratory system
Z87.19 Personal history of other diseases of the digestive system
Z87.798 Personal history of other (corrected) congenital malformations
Z87.820 Personal history of traumatic brain injury
Z88.9 Allergy status to unspecified drugs, medicaments, and biological substances status
Z91.09 Other allergy status, other than to drugs and biological substances
Z91.128 Patient's intentional underdosing of medication regimen for other reason (report drug code)
Z91.138 Patient's unintentional underdosing of medication regimen for other reason (report drug code)
Z91.14 Patient's other noncompliance with medication regimen
Z91.19 Patient's noncompliance with other medical treatment and regimen
Z91.411 Personal history of adult psychological abuse

+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.

Continuum Model for ADHD

The following continuum model from *Coding for Pediatrics 2014* has been devised to express the various levels of service for ADHD. This model demonstrates the cumulative effect of the key criteria for each level of service using a single diagnosis as the common denominator. It also shows the importance of other variables, such as patient age, duration and severity of illness, social contexts, and comorbid conditions that often have key roles in pediatric cases.

Quick Reference for Office or Other Outpatient Codes Used in Continuum for ADHD ^a				
E/M Code Level	History	Examination	MDM	Time
99211 ^b	NA	NA	NA	5 minutes
99212	Problem-focused	Problem-focused	Straightforward	10 minutes
99213	Expanded problem-focused	Expanded problem-focused	Low	15 minutes
99214	Detailed	Detailed	Moderate	25 minutes
99215	Comprehensive	Comprehensive	High	40 minutes
Abbreviations: E/M, evaluation and management; MDM, medical decision-making; NA, not applicable. ^a Use of a code level requires that you meet or exceed 2 of the 3 key components based on medical necessity. ^b Low level E/M service that may not require the presence of a physician.				

Adapted from American Academy of Pediatrics. *Coding for Pediatrics 2015: A Manual for Pediatric Documentation and Payment*. 20th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015.

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Continuum Model for Attention-Deficit/Hyperactivity Disorder (ADHD)

CPT Code Vignette

99211*

Nurse visit to follow up growth or blood pressure prior to renewing prescription for psychoactive drugs

**There are no required key components; however, the nurse must document his or her history, physical examination, and assessment to support medical necessity.*

99212

Follow-up visit to recheck prior weight loss in patient with established ADHD otherwise stable on stimulant medication

99213

3- to 6-month follow-up of child with ADHD who is presently doing well using medication and without other problems

History

1. Chief complaint
2. Brief HPI, existing medications, and desired/undesired effects

Problem focused

1. Chief complaint
2. Document brief HPI, existing medications, and desired/undesired effects

Expanded problem focused

1. Reason for the visit
2. Review of medications
3. Effect of medication on appetite, mood, sleep
4. Quality of schoolwork (eg, review report cards)
5. Absence of tics
6. Problem-pertinent ROS

Physical Examination

1. Weight, blood pressure
2. Overall appearance

Problem focused

1. Weight, blood pressure
2. Overall appearance

Expanded problem focused

1. General multisystem examination or single organ system examination with special reference to neurologic examination
2. Rating Scale Review: Teacher Vanderbilt ADHD Rating Scale results reviewed

Medical Decision-making

1. Refill existing prescription

Straightforward

1. Refill existing prescription

Low complexity

1. Review rating scale results and feedback materials from teacher.
2. Discuss 6-month treatment plan with adjustment of medication.
3. Plan for further monitoring.

Continuum Model for Attention-Deficit/Hyperactivity Disorder (ADHD), continued

CPT Code Vignette	History	Physical Examination	Medical Decision-making
99214 Follow-up evaluation of an established patient with ADHD with failure to improve on medication and/or weight loss	Detailed All data implicit in 99213 expanded plus pertinent review of PFSH and extended ROS including gastrointestinal and psychiatric	Detailed 1. General multisystem examination or detailed single organ system examination of the neurologic system 2. Rating Scale Review: Parent and Teacher Vanderbilt ADHD Rating Scales results reviewed	Moderate complexity Discussion of possible interventions including, but not limited to, 1. Educational intervention 2. Alteration in medications 3. Obtaining drug levels 4. Psychiatric intervention 5. Behavioral modification program
99215 Initial evaluation of an established patient experiencing difficulty in classroom, home, or social situation and suspected of having ADHD This could be billed as a consultation if the established patient is referred by school for opinion or advice (not transfer of care) and the criteria for reporting a consultation are met.	Comprehensive 1. Chief complaint 2. History of the problem, extended 3. Complete PFSH 4. Complete ROS	Comprehensive 1. General multisystem examination with special attention to neurologic examination and mental health status 2. Rating Scale Review: Parent and Teacher Vanderbilt ADHD Rating Scales results reviewed	High complexity Review of Vanderbilt scores, school record, any other formal evaluations completed to date, discussion of differential diagnoses, possible interventions including, but not limited to, 1. Educational interventions 2. Initiation of medications 3. Obtaining drug levels or rule out substance abuse, if appropriate 4. Laboratory tests as indicated (eg, complete blood cell count and iron studies, serum lead levels) 5. Psychological and/or psychiatric interventions 6. Behavioral modification program 7. Consideration of neurology consultation 8. Coordination of care services with school, family, and other providers

Understanding ADHD: Information for Parents About Attention-Deficit/Hyperactivity Disorder



Almost all children have times when their behavior veers out of control. They may speed about in constant motion, make noise nonstop, refuse to wait their turn, and crash into everything around them. At other times they may drift as if in a daydream, unable to pay attention or finish what they start.

However, for some children, these kinds of behaviors are more than an occasional problem. Children with attention-deficit/hyperactivity disorder (ADHD) have behavior problems that are so frequent and severe that they interfere with their ability to live normal lives.

These children often have trouble getting along with siblings and other children at school, at home, and in other settings. Those who have trouble paying attention usually have trouble learning. An impulsive nature may put them in actual physical danger. Because children with ADHD have difficulty controlling this behavior, they may be labeled “bad kids” or “space cadets.”

Left untreated, ADHD in some children will continue to cause serious, lifelong problems, such as poor grades in school, run-ins with the law, failed relationships, and the inability to keep a job.

Effective treatment is available. If your child has ADHD, your pediatrician can offer a long-term treatment plan to help your child lead a happy and healthy life. As a parent, you have a very important role in this treatment.

What is ADHD?

ADHD is a condition of the brain that makes it difficult for children to control their behavior. It is one of the most common chronic conditions of childhood. It affects 4% to 12% of school-aged children. ADHD is diagnosed in about 3 times more boys than girls.

The condition affects behavior in specific ways.

What are the symptoms of ADHD?

ADHD includes 3 groups of behavior symptoms: inattention, hyperactivity, and impulsivity. Table 1 explains these symptoms.

Are there different types of ADHD?

Not all children with ADHD have all the symptoms. They may have one or more of the symptom groups listed in Table 1. The symptoms usually are classified as the following types of ADHD:

- **Inattentive only** (formerly known as attention-deficit disorder [ADD])—Children with this form of ADHD are not overly active. Because they do not disrupt the classroom or other activities, their symptoms may not be noticed. Among girls with ADHD, this form is more common.
- **Hyperactive/impulsive**—Children with this type of ADHD show both hyperactive and impulsive behavior, but they can pay attention. They are the least common group and are frequently younger.
- **Combined inattentive/hyperactive/impulsive**—Children with this type of ADHD show a number of symptoms in all 3 dimensions. It is the type that most people think of when they think of ADHD.

TABLE 1. Symptoms of ADHD

Symptom	How a child with this symptom may behave
Inattention	Often has a hard time paying attention, daydreams
	Often does not seem to listen
	Is easily distracted from work or play
	Often does not seem to care about details, makes careless mistakes
	Frequently does not follow through on instructions or finish tasks
	Is disorganized
	Frequently loses a lot of important things
	Often forgets things
	Frequently avoids doing things that require ongoing mental effort
Hyperactivity	Is in constant motion, as if “driven by a motor”
	Cannot stay seated
	Frequently squirms and fidgets
	Talks too much
	Often runs, jumps, and climbs when this is not permitted
	Cannot play quietly
Impulsivity	Frequently acts and speaks without thinking
	May run into the street without looking for traffic first
	Frequently has trouble taking turns
	Cannot wait for things
	Often calls out answers before the question is complete
	Frequently interrupts others

How can I tell if my child has ADHD?

Remember, it is normal for all children to show some of these symptoms from time to time. Your child may be reacting to stress at school or home. She may be bored or going through a difficult stage of life. It does not mean she has ADHD.

Sometimes a teacher is the first to notice inattention, hyperactivity, and/or impulsivity and bring these symptoms to the parents' attention.

Perhaps questions from your pediatrician raised the issue. At routine visits, pediatricians often ask questions such as

- How is your child doing in school?
- Are there any problems with learning that you or your child's teachers have seen?
- Is your child happy in school?

- Is your child having problems completing class work or homework?
- Are you concerned with any behavior problems in school, at home, or when your child is playing with friends?

Your answers to these questions may lead to further evaluation for ADHD.

If your child has shown symptoms of ADHD on a regular basis for more than 6 months, discuss this with your pediatrician.

Diagnosis

Your pediatrician will determine whether your child has ADHD using standard guidelines developed by the American Academy of Pediatrics. These diagnosis guidelines are specifically for children 4 to 18 years of age.

It is difficult to diagnose ADHD in children younger than 4 years. This is because younger children change very rapidly. It is also more difficult to diagnose ADHD once a child becomes a teenager.

There is no single test for ADHD. The process requires several steps and involves gathering a lot of information from multiple sources. You, your child, your child's school, and other caregivers should be involved in assessing your child's behavior.

Children with ADHD show signs of inattention, hyperactivity, and/or impulsivity in specific ways. (See the behaviors listed in Table 1.) Your pediatrician will look at how your child's behavior compares to that of other children her own age, based on the information reported about your child by you, her teacher, and any other caregivers who spend time with your child, such as coaches or child care workers.

The following guidelines are used to confirm a diagnosis of ADHD.

- Symptoms occur in 2 or more settings, such as home, school, and social situations, and cause some impairment.
- In a child 4 to 17 years of age, 6 or more symptoms must be identified.
- In a child 17 years and older, 5 or more symptoms must be identified.
- Symptoms significantly impair your child's ability to function in some of the activities of daily life, such as schoolwork, relationships with you and siblings, relationships with friends, or the ability to function in groups such as sports teams.
- Symptoms start before the child reaches 12 years of age. However, these may not be recognized as ADHD symptoms until a child is older.
- Symptoms have continued for more than 6 months.

In addition to looking at your child's behavior, your pediatrician will do a physical and neurologic examination. A full medical history will be needed to put your child's behavior in context and screen for other conditions that may affect her behavior. Your pediatrician also will talk with your child about how your child acts and feels.

Your pediatrician may refer your child to a pediatric subspecialist or mental health clinician if there are concerns in one of the following areas:

- Intellectual disability (mental retardation)
- Developmental disorder such as speech problems, motor problems, or a learning disability
- Chronic illness being treated with a medication that may interfere with learning
- Trouble seeing and/or hearing
- History of abuse
- Major anxiety or major depression
- Severe aggression
- Possible seizure disorder
- Possible sleep disorder

Keep safety in mind

If your child shows any symptoms of ADHD, it is very important that you pay close attention to safety. A child with ADHD may not always be aware of dangers and can get hurt easily. Be especially careful around

- Traffic
- Firearms
- Swimming pools
- Tools such as lawn mowers
- Poisonous chemicals, cleaning supplies, or medicines

How can parents help with the diagnosis?

As a parent, you will provide crucial information about your child's behavior and how it affects her life at home, in school, and in other social settings. Your pediatrician will want to know what symptoms your child is showing, how long the symptoms have occurred, and how the behavior affects your child and your family. You may need to fill in checklists or rating scales about your child's behavior.

In addition, sharing your family history can offer important clues about your child's condition.

How will my child's school be involved?

For an accurate diagnosis, your pediatrician will need to get information about your child directly from your child's classroom teacher or another school professional. Children at least 4 years and older spend many of their waking hours at preschool or school. Teachers provide valuable insights. Your child's teacher may write a report or discuss the following with your pediatrician:

- Your child's behavior in the classroom
- Your child's learning patterns
- How long the symptoms have been a problem
- How the symptoms are affecting your child's progress at school
- Ways the classroom program is being adapted to help your child
- Whether other conditions may be affecting the symptoms

In addition, your pediatrician may want to see report cards, standardized tests, and samples of your child's schoolwork.

How will others who care for my child be involved?

Other caregivers may also provide important information about your child's behavior. Former teachers, religious and scout leaders, or coaches may have valuable input. If your child is homeschooled, it is especially important to assess his behavior in settings outside of the home.

Your child may not behave the same way at home as he does in other settings. Direct information about the way your child acts in more than one setting is required. It is important to consider other possible causes of your child's symptoms in these settings.

In some cases, other mental health care professionals may also need to be involved in gathering information for the diagnosis.

Coexisting conditions

As part of the diagnosis, your pediatrician will look for other conditions that show the same types of symptoms as ADHD. Your child may simply have a different condition or ADHD and another condition. Most children with a diagnosis of ADHD have at least one coexisting condition.

Common coexisting conditions include

- **Learning disabilities**—Learning disabilities are conditions that make it difficult for a child to master specific skills such as reading or math. ADHD is not a learning disability. However, ADHD can make it hard for a child to do well in school. Diagnosing learning disabilities requires evaluations, such as IQ and academic achievement tests, and it requires educational interventions.
- **Oppositional defiant disorder or conduct disorder**—Up to 35% of children with ADHD also have oppositional defiant disorder or conduct disorder. Children with oppositional defiant disorder tend to lose their temper easily and annoy people on purpose, and they are defiant and hostile toward authority figures. Children with conduct disorder break rules, destroy property, get suspended or expelled from school, and violate the rights of other people. Children with coexisting conduct disorder are at much higher risk for getting into trouble with the law or having substance abuse problems than children who have only ADHD. Studies show that this type of coexisting condition is more common among children with the primarily hyperactive/impulsive and combination types of ADHD. Your pediatrician may recommend behavioral therapy for your child if she has this condition.
- **Mood disorders/depression**—About 18% of children with ADHD also have mood disorders such as depression or bipolar disorder (formerly called manic depression). There is frequently a family history of these types of disorders. Coexisting mood disorders may put children at higher risk for suicide, especially during the teenage years. These disorders are more common among children with inattentive and combined types of ADHD. Children with mood disorders or depression often require additional interventions or a different type of medication than those normally used to treat ADHD.
- **Anxiety disorders**—These affect about 25% of children with ADHD. Children with anxiety disorders have extreme feelings of fear, worry, or panic that make it difficult to function. These disorders can produce physical symptoms such as racing pulse, sweating, diarrhea, and nausea. Counseling and/or different medication may be needed to treat these coexisting conditions.
- **Language disorders**—Children with ADHD may have difficulty with how they use language. It is referred to as a pragmatic language disorder. It may not show up with standard tests of language. A speech and language clinician can detect it by observing how a child uses language in her day-to-day activities.

Are there other tests for ADHD?

You may have heard theories about other tests for ADHD. There are no other proven tests for ADHD at this time.

Many theories have been presented, but studies have shown that the following tests have little value in diagnosing an individual child:

- Screening for high lead levels in the blood
- Screening for thyroid problems
- Computerized continuous performance tests
- Brain imaging studies such as CAT scans and MRIs
- Electroencephalogram (EEG) or brain-wave test

While these tests are not helpful in diagnosing ADHD, your pediatrician may see other signs or symptoms in your child that warrant blood tests, brain imaging studies, or an EEG.

What causes ADHD?

ADHD is one of the most studied conditions of childhood, but ADHD may be caused by a number of things.

Research to date has shown

- ADHD is a neurobiologic condition whose symptoms are also dependent on the child's environment.
- A lower level of activity in the parts of the brain that control attention and activity level may be associated with ADHD.
- ADHD frequently runs in families. Sometimes ADHD is diagnosed in a parent at the same time it is diagnosed in the child.
- In very rare cases, toxins in the environment may lead to ADHD. For instance, lead in the body can affect child development and behavior. Lead may be found in many places, including homes built before 1978 when lead was added to paint.
- Significant head injuries may cause ADHD in some cases.
- Prematurity increases the risk of developing ADHD.
- Prenatal exposures, such as alcohol or nicotine from smoking, increase the risk of developing ADHD.

There is little evidence that ADHD is caused by

- Eating too much sugar
- Food additives
- Allergies
- Immunizations

Treatment

Once the diagnosis is confirmed, the outlook for most children who receive treatment for ADHD is encouraging. There is no specific cure for ADHD, but there are many treatment options available.

Each child's treatment must be tailored to meet his individual needs. In most cases, treatment for ADHD should include

- A long-term management plan with
 - Target outcomes for behavior
 - Follow-up activities
 - Monitoring
- Education about ADHD
- Teamwork among doctors, parents, teachers, caregivers, other health care professionals, and the child
- Medication
- Behavior therapy including parent training
- Individual and family counseling

Treatment for ADHD uses the same principles that are used to treat other chronic conditions like asthma or diabetes. Long-term planning is needed because these conditions are not cured. Families must manage them on an ongoing basis. In the case of ADHD, schools and other caregivers must also be involved in managing the condition.

Educating the people involved about ADHD is a key part of treating your child. As a parent, you will need to learn about ADHD. Read about the condition and talk with people who understand it. This will help you manage the ways ADHD affects your child and your family on a day-to-day basis. It will also help your child learn to help himself.

Setting target outcomes

At the beginning of treatment, your pediatrician should help you set around 3 target outcomes (goals) for your child's behavior. These target outcomes will guide the treatment plan. Your child's target outcomes should focus

Table 2. Common medications

Type of medication	Brand name	Generic name	Duration
Short-acting amphetamine stimulants	Adderall	Mixed amphetamine salts	4 to 6 hours
	Dexedrine	Dextroamphetamine	4 to 6 hours
	Dextrostat	Dextroamphetamine	4 to 6 hours
Short-acting methylphenidate stimulants	Focalin	Dexmethylphenidate	4 to 6 hours
	Methylin	Methylphenidate (tablet, liquid, and chewable tablets)	3 to 5 hours
	Ritalin	Methylphenidate	3 to 5 hours
Intermediate-acting methylphenidate stimulants	Metadate CD	Extended-release methylphenidate	6 to 8 hours
	Ritalin LA	Extended-release methylphenidate	6 to 8 hours
Long-acting amphetamine stimulants	Adderall-XR	Extended-release amphetamine	10 to 12 hours
	Dexedrine Spansule	Extended-release amphetamine	6+ hours
	Vyvanse	Lisdexamfetamine	10 to 12 hours
Long-acting methylphenidate stimulants	Concerta	Extended-release methylphenidate	10 to 12 hours
	Daytrana	Extended-release methylphenidate (skin patch)	11 to 12 hours
	Focalin XR	Extended-release dexmethylphenidate	8 to 12 hours
	Quillivant XR	Extended-release methylphenidate (liquid)	10 to 12 hours
Long-acting non-stimulants	Intuniv	Guanfacine	24 hours
	Kapvay	Clonidine	12 hours
	Strattera	Atomoxetine	24 hours

Products are mentioned for informational purposes only and do not imply an endorsement by the American Academy of Pediatrics. Your doctor or pharmacist can provide you with important safety information for the products listed.

on helping her function as well as possible at home, at school, and in your community. You need to identify what behaviors are most preventing your child from success.

The following are examples of target outcomes:

- Improved relationships with parents, siblings, teachers, and friends (eg, fewer arguments with brothers or sisters or being invited more frequently to friends' houses or parties)
- Better schoolwork (eg, completing class work or homework assignments)
- More independence in self-care or homework (eg, getting ready for school in the morning without supervision)
- Improved self-esteem (eg, increase in feeling that she can get her work done)

- Fewer disruptive behaviors (eg, decrease in the number of times she refuses to obey rules)
- Safer behavior in the community (eg, when crossing streets)

The target outcomes should be

- Realistic
- Something your child will be able to do
- Behaviors that you can observe and count (eg, with rating scales)

Your child's treatment plan will be set up to help her achieve these goals.

Medication

For most children, stimulant medications are a safe and effective way to relieve ADHD symptoms. As glasses help people focus their eyes to see, these medications help children with ADHD focus their thoughts better and ignore distractions. This makes them more able to pay attention and control their behavior.

Stimulants may be used alone or combined with behavior therapy. Studies show that about 80% of children with ADHD who are treated with stimulants improve a great deal once the right medication and dose are determined.

Two forms of stimulants are available: immediate-release (short-acting) and extended-release (intermediate-acting and long-acting). (See Table 2.) Immediate-release medications usually are taken every 4 hours, when needed. They are the cheapest of the medications. Extended-release medications usually are taken once in the morning.

Children who use extended-release forms of stimulants can avoid taking medication at school or after school. It is important not to chew or crush extended-release capsules or tablets. However, extended-release capsules that are made up of beads can be opened and sprinkled onto food for children who have difficulties swallowing tablets or capsules.

Non-stimulants can be tried when stimulant medications don't work or cause bothersome side effects.

Which medication is best for my child?

It may take some time to find the best medication, dosage, and schedule for your child.

Your child may need to try different types of stimulants or other medication. Some children respond to one type of stimulant but not another.

The amount of medication (dosage) that your child needs also may need to be adjusted. The dosage is not based solely on his weight. Your pediatrician will vary the dosage over time to get the best results and control possible side effects.

The medication schedule also may be adjusted depending on the target outcome. For example, if the goal is to get relief from symptoms mostly at school, your child may take the medication only on school days.

It is important for your child to have regular medical checkups to monitor how well the medication is working and check for possible side effects.

What side effects can stimulants cause?

Side effects occur sometimes. These tend to happen early in treatment and are usually mild and short-lived, but in rare cases they can be prolonged or more severe.

The most common side effects include

- Decreased appetite/weight loss
- Sleep problems
- Social withdrawal

Principles for behavior therapy

Behavior therapy has 3 basic principles.

- 1. Set specific doable goals.** Set clear and reasonable goals for your child, such as staying focused on homework for a certain amount of time or sharing toys with friends.
- 2. Provide rewards and consequences.** Give your child a specified reward (positive reinforcement) every time she shows the desired behavior. Give your child a consequence (unwanted result or punishment) consistently when she has inappropriate behaviors.
- 3. Keep using the rewards and consequences.** Using the rewards and consequences consistently for a long time will shape your child's behavior in a positive way.

Some less common side effects include

- Rebound effect (increased activity or a bad mood as the medication wears off)
- Transient muscle movements or sounds called tics
- Minor growth delay

Very rare side effects include

- Significant increase in blood pressure or heart rate
- Bizarre behaviors

The same sleep problems do not exist for atomoxetine, but initially it may make your child sleepy or upset her stomach. There have been very rare cases of atomoxetine needing to be stopped because it was causing liver damage. Rarely atomoxetine increased thoughts of suicide. Guanfacine can cause drowsiness, fatigue, or a decrease in blood pressure.

More than half of children who have tic disorders, such as Tourette syndrome, also have ADHD. Tourette syndrome is an inherited condition associated with frequent tics and unusual vocal sounds. The effect of stimulants on tics is not predictable, although most studies indicate that stimulants are safe for children with ADHD and tic disorders in most cases. It is also possible to use atomoxetine or guanfacine for children with ADHD and Tourette syndrome. Most side effects can be relieved by

- Changing the medication dosage
- Adjusting the schedule of medication
- Using a different stimulant or trying a non-stimulant (See Table 2.)

Close contact with your pediatrician is required until you find the best medication and dose for your child. After that, periodic monitoring by your doctor is important to maintain the best effects. To monitor the effects of the medication, your pediatrician will probably have you and your child's teacher(s) fill out behavior rating scales; observe changes in your child's target goals; notice any side effects; and monitor your child's height, weight, pulse, and blood pressure.

Stimulants, atomoxetine, and guanfacine may not be an option for children who are taking certain other medications or who have some medical conditions, such as congenital heart disease.

Behavior therapy

Most experts recommend using both medication and behavior therapy to treat ADHD. This is known as a multimodal treatment approach.

There are many forms of behavior therapy, but all have a common goal—to change the child's physical and social environments to help the child improve his behavior.

Table 3. Behavior therapy techniques

Technique	Description	Example
Positive reinforcement	Complimenting and providing rewards or privileges in response to desired behavior.	Child completes an assignment and is permitted to play on the computer.
Time-out	Removing access to desired activity because of unwanted behavior.	Child hits sibling and, as a result, must sit for 5 minutes in the corner of the room.
Response cost	Withdrawing rewards or privileges because of unwanted behavior.	Child loses free-time privileges for not completing homework.
Token economy	Combining reward and consequence. Child earns rewards and privileges when performing desired behaviors. She loses rewards and privileges as a result of unwanted behavior.	Child earns stars or points for completing assignments and loses stars for getting out of seat. Child cashes in the sum of her stars at the end of the week for a prize.

Under this approach, parents, teachers, and other caregivers learn better ways to work with and relate to the child with ADHD. You will learn how to set and enforce rules, help your child understand what he needs to do, use discipline effectively, and encourage good behavior. Your child will learn better ways to control his behavior as a result. You will learn how to be more consistent.

Table 3 shows specific behavior therapy techniques that can be effective with children with ADHD.

Behavior therapy recognizes the limits that having ADHD puts on a child. It focuses on how the important people and places in the child's life can adapt to encourage good behavior and discourage unwanted behavior. It is different from play therapy or other therapies that focus mainly on the child and his emotions.

How can I help my child control her behavior?

As the child's primary caregivers, parents play a major role in behavior therapy. Parent training is available to help you learn more about ADHD and specific, positive ways to respond to ADHD-type behaviors. This will help your child improve. In many cases parenting classes with other parents will be sufficient, but with more challenging children, individual work with a counselor/coach may be needed.

Taking care of yourself also will help your child. Being the parent of a child with ADHD can be tiring and trying. It can test the limits of even the best parents. Parent training and support groups made up of other families who are dealing with ADHD can be a great source of help. Learn stress-management techniques to help you respond calmly to your child. Seek counseling if you feel overwhelmed or hopeless.

Ask your pediatrician to help you find parent training, counseling, and support groups in your community. Additional resources are listed at the end of this publication.

Tips for helping your child control his behavior

- **Keep your child on a daily schedule.** Try to keep the time that your child wakes up, eats, bathes, leaves for school, and goes to sleep the same each day.
- **Cut down on distractions.** Loud music, computer games, and TV can be overstimulating to your child. Make it a rule to keep the TV or music off during mealtime and while your child is doing homework. Don't place a TV in your child's bedroom. Whenever possible, avoid taking your child to places that may be too stimulating, such as busy shopping malls.
- **Organize your house.** If your child has specific and logical places to keep his schoolwork, toys, and clothes, he is less likely to lose them. Save a spot near the front door for his school backpack so he can grab it on the way out the door.
- **Reward positive behavior.** Offer kind words, hugs, or small prizes for reaching goals in a timely manner or good behavior. Praise and reward your child's efforts to pay attention.
- **Set small, reachable goals.** Aim for slow progress rather than instant results. Be sure that your child understands that he can take small steps toward learning to control himself.
- **Help your child stay "on task."** Use charts and checklists to track progress with homework or chores. Keep instructions brief. Offer frequent, friendly reminders.
- **Limit choices.** Help your child learn to make good decisions by giving him only 2 or 3 options at a time.
- **Find activities at which your child can succeed.** All children need to experience success to feel good about themselves.
- **Use calm discipline.** Use consequences such as time-out, removing the child from the situation, or distraction. Sometimes it is best to simply ignore the behavior. Physical punishment, such as spanking or slapping, is *not* helpful. Discuss your child's behavior with him when both of you are calm.
- **Develop a good communication system with your child's teacher** so that you can coordinate your efforts and monitor your child's progress.

How can my child's school help?

Your child's school is a key partner in providing effective behavior therapy for your child. In fact, these principles work well in the classroom for most students.

Classroom management techniques may include

- Keeping a set routine and schedule for activities
- Using a system of clear rewards and consequences, such as a point system or token economy (See Table 3.)
- Sending daily or weekly report cards or behavior charts to parents to inform them about the child's progress
- Seating the child near the teacher
- Using small groups for activities
- Encouraging students to pause a moment before answering questions
- Keeping assignments short or breaking them into sections
- Close supervision with frequent, positive cues to stay on task
- Changes to where and how tests are given so students can succeed (eg, allowing students to take tests in a less distracting environment or allowing more time to complete tests)

Your child's school should work with you and your pediatrician to develop strategies to assist your child in the classroom. When a child has ADHD that is severe enough to interfere with her ability to learn, 2 federal laws offer help. These laws require public schools to cover costs of evaluating the educational needs of the affected child and providing the needed services.

1. The Individuals with Disabilities Education Act, Part B (IDEA) requires public schools to cover costs of evaluating the educational needs of the affected child and providing the needed special education services if your child qualifies because her learning is impaired by her ADHD.
2. Section 504 of the Rehabilitation Act of 1973 does not have strict qualification criteria but is limited to changes in the classroom, modifications in homework assignments, and taking tests in a less distracting environment or allowing more time to complete tests.

If your child has ADHD and a coexisting condition, she may need additional special services such as a classroom aide, private tutoring, special classroom settings or, in rare cases, a special school.

It is important to remember that once ADHD is diagnosed and treated, children with it are more likely to achieve their goals in school.

Keeping the treatment plan on track

Ongoing monitoring of your child's behavior and medications is required to find out if the treatment plan is working. Office visits, phone conversations, behavior checklists, written reports from teachers, and behavior report cards are common tools for following the child's progress.

Treatment plans for ADHD usually require long-term efforts on the part of families and schools. Medication schedules may be complex. Behavior therapies require education and patience. Sometimes it can be hard for everyone to stick with it. Your efforts play an important part in building a healthy future for your child.

Ask your pediatrician to help you find ways to keep your child's treatment plan on track.

What if my child does not reach his target outcomes?

Most school-aged children with ADHD respond well when their treatment plan includes both medication and behavior therapy. If your child is not achieving his goals, your pediatrician will assess the following factors:

- Were the target outcomes realistic?
- Is more information needed about the child's behavior?
- Is the diagnosis correct?
- Is another condition hindering treatment?
- Is the treatment plan being followed?
- Has the treatment failed?

While treatment for ADHD should improve your child's behavior, **it may not completely eliminate the symptoms** of inattention, hyperactivity, and impulsivity. Children who are being treated successfully may still have trouble with their friends or schoolwork.

However, if your child clearly is not meeting his specific target outcomes, your pediatrician will need to reassess the treatment plan.

Unproven treatments

You may have heard media reports or seen advertisements for "miracle cures" for ADHD. Carefully research any such claims. Consider whether the source of the information is valid. At this time, there is no scientifically proven cure for this condition.

Teenagers with ADHD

The teenage years can be a special challenge. Academic and social demands increase. In some cases, symptoms may be better controlled as the child grows older; however, frequently the demands for performance also increase so that in most cases, ADHD symptoms persist and continue to interfere with the child's ability to function adequately. According to the National Institute of Mental Health, about 80% of those who required medication for ADHD as children still need it as teenagers.

Parents play an important role in helping teenagers become independent. Encourage your teenager to help herself with strategies such as

- Using a daily planner for assignments and appointments
- Making lists
- Keeping a routine
- Setting aside a quiet time and place to do homework
- Organizing storage for items such as school supplies, clothes, CDs, and sports equipment
- Being safety conscious (eg, always wearing seat belts, using protective gear for sports)
- Talking about problems with someone she trusts
- Getting enough sleep
- Understanding her increased risk of abusing substances such as tobacco and alcohol

Activities such as sports, drama, and debate teams can be good places to channel excess energy and develop friendships. Find what your teenager does well and support her efforts to "go for it."

Milestones such as learning to drive and dating offer new freedom and risks. Parents must stay involved and set limits for safety. Your child's ADHD increases her risk of incurring traffic violations and accidents.

It remains important for parents of teenagers to keep in touch with teachers and make sure that their teenager's schoolwork is going well.

Talk with your pediatrician if your teenager shows signs of severe problems such as depression, drug abuse, or gang-related activities.

The following methods **need more scientific evidence to prove that they work:**

- Megavitamins and mineral supplements
- Anti-motion-sickness medication (to treat the inner ear)
- Treatment for candida yeast infection
- EEG biofeedback (training to increase brain-wave activity)
- Applied kinesiology (realigning bones in the skull)
- Reducing sugar consumption
- Optometric vision training (asserts that faulty eye movement and sensitivities cause the behavior problems)

Always tell your pediatrician about any alternative therapies, supplements, or medications that your child is using. These may interact with prescribed medications and harm your child.

Will there be a cure for ADHD soon?

While there are no signs of a cure at this time, research is ongoing to learn more about the role of the brain in ADHD and the best ways to treat the

disorder. Additional research is looking at the long-term outcomes for people with ADHD.

Frequently asked questions

Will my child outgrow ADHD?

ADHD continues into adulthood in most cases. However, by developing their strengths, structuring their environments, and using medication when needed, adults with ADHD can lead very productive lives. In some careers, having a high-energy behavior pattern can be an asset.

Why do so many children have ADHD?

The number of children getting treatment for ADHD has risen. It is not clear whether more children have ADHD or more children are receiving a diagnosis of ADHD. Also, more children with ADHD are getting treatment for a longer period. ADHD is now one of the most common and most studied conditions of childhood. Because of more awareness and better ways of diagnosing and treating this disorder, more children are being helped. It may also be the case that school performance has become more important because of the higher technical demand of many jobs, and ADHD frequently interferes with school functioning.

Are schools putting children on ADHD medication?

Teachers are often the first to notice behavior signs of possible ADHD. However, only physicians can prescribe medications to treat ADHD. The diagnosis of ADHD should follow a careful process.

Are children getting high on stimulant medications?

When taken as directed by a doctor, there is no evidence that children are getting high on stimulant drugs such as methylphenidate and amphetamine. At therapeutic doses, these drugs also do not sedate or tranquilize children and do not increase the risk of addiction.

Stimulants are classified as Schedule II drugs by the US Drug Enforcement Administration because there is abuse potential of this class of medication. If your child is on medication, it is always best to supervise the use of the medication closely. Atomoxetine and guanfacine are not Schedule II drugs because they don't have abuse potential, even in adults.

Are stimulant medications gateway drugs leading to illegal drug or alcohol abuse?

People with ADHD are naturally impulsive and tend to take risks. But patients with ADHD who are taking stimulants are not at a greater risk and actually may be at a lower risk of using other drugs. Children and teenagers who have ADHD and also have coexisting conditions may be at higher risk for drug and alcohol abuse, regardless of the medication used.

Resources

The following is a list of support groups and additional resources for further information about ADHD. Check with your pediatrician for resources in your community.

National Resource Center on AD/HD

www.help4adhd.org

Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)

800/233-4050

www.chadd.org

Attention Deficit Disorder Association

856/439-9099

www.add.org**National Dissemination Center for Children with Disabilities**

800/695-0285

www.nichcy.org**National Institute of Mental Health**

866/615-6464

www.nimh.nih.gov**National Tourette Syndrome Association, Inc**

800/237-0717

www.tsa-usa.org

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medicines for ADHD

questions from teens

who have ADHD



Q: What can I do besides taking medicines?

A: Medicines and behavior therapies are the only treatments that have been shown by scientific studies to work consistently for ADHD symptoms. Medicines are prescribed by a doctor, while behavior therapies usually are done with a trained counselor in behavior treatment. These 2 treatments are probably best used together, but you might be able to do well with one or the other. You can't rely on other treatments such as biofeedback, allergy treatments, special diets, vision training, or chiropractic because there isn't enough evidence that shows they work.

Counseling may help you learn how to cope with some issues you may face. And there are things you can do to help yourself. For example, things that may help you stay focused include using a daily planner for schoolwork and other activities, making to-do lists, and even getting enough sleep. Counseling can help you find an organization system or a checklist.

Q: How can medicines help me?

A: There are several different ADHD medicines. They work by causing the brain to have more *neurotransmitters* in the right places. Neurotransmitters are chemicals in the brain that help us focus our attention, control our impulses, organize and plan, and stick to routines. Medicines for ADHD can help you focus your thoughts and ignore distractions so that you can reach your full potential. They also can help you control your emotions and behavior. Check with your doctor to learn more about this.

Q: Are medicines safe?

A: For most teens with ADHD, stimulant medicines are safe and effective if taken as recommended. However, like most medicines, there could be side effects. Luckily, the side effects tend to happen early on, are usually mild, and don't last too long. If you have any side effects, tell your doctor. Changes may need to be made in your medicines or their dosages.

- **Most common side effects** include decreased appetite or weight loss, problems falling asleep, headaches, jitteriness, and stomachaches.
- **Less common side effects** include a bad mood as medicines wear off (called the rebound effect) and facial twitches or tics.

Q: Will medicines change my personality?

A: Medicines won't change who you are and should not change your personality. If you notice changes in your mood or personality, tell your doctor. Occasionally when medicines wear off, some teens become more irritable for a short time. An adjustment of the medicines by your doctor may be helpful.

Q: Will medicines affect my growth?

A: Medicines will not keep you from growing. Significant growth delay is a very rare side effect of some medicines prescribed for ADHD. Most scientific studies show that taking these medicines has little to no long-term effect on growth in most cases.

Q: Do I need to take medicines at school?

A: There are 3 types of medicines used for teens with ADHD: **short acting** (immediate release), **intermediate acting**, and **long acting**. You can avoid taking medicines at school if you take the intermediate- or long-acting kind. Long-acting medicines usually are taken once in the morning or evening. Short-acting medicines usually are taken every 4 hours.

Q: Does taking medicines make me a drug user?

A: No! Although you may need medicines to help you stay in control of your behavior, medicines used to treat ADHD do not lead to drug abuse. In fact, taking medicines as prescribed by your doctor and doing better in school may help you avoid drug use and abuse. (But never give or share your medicines with anyone else.)

Q: Will I have to take medicines forever?

A: In most cases, ADHD continues later in life. Whether you need to keep taking medicines as an adult depends on your own needs. The need for medicines may change over time. Many adults with ADHD have learned how to succeed in life without medicines by using behavior therapies or finding jobs that suit their strengths and weaknesses.

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what is ADHD?

questions from teens



Attention-deficit/hyperactivity

disorder (ADHD) is a condition of the brain that makes it difficult for people to concentrate or pay attention in certain areas where it is easy for others, like school or homework. The following are quick answers to some common questions:

Q: What causes ADHD?

A: There isn't just one cause. Research shows that

- ADHD is a medical condition caused by small changes in how the brain works. It seems to be related to 2 chemicals in your brain called *dopamine* and *norepinephrine*. These chemicals help send messages between nerve cells in the brain—especially those areas of the brain that control attention and activity level.
- ADHD most often runs in families.
- In a few people with ADHD, being born prematurely or being exposed to alcohol during the pregnancy can contribute to ADHD.
- Immunizations and eating too much sugar do NOT cause ADHD. And there isn't enough evidence that shows allergies and food additives cause ADHD.

Q: How can you tell if someone has ADHD?

A: You can't tell if someone has ADHD just by looks. People with ADHD don't look any different, but how they act may make them stand out from the crowd. Some people with ADHD are very hyperactive (they move around a lot and are not able to sit still) and have behavior problems that are obvious to everyone. Other people with ADHD are quiet and more laid back on the outside, but on the inside struggle with attention to schoolwork and other tasks. They are distracted by people and things around them when they try to study; they may have trouble organizing schoolwork or forget to turn in assignments.

Q: Can ADHD cause someone to act up or get in trouble?

A: Having ADHD can cause you to struggle in school or have problems controlling your behavior. Some people may say or think that your struggles and problems are because you are bad, lazy, or not smart. But they're wrong. It's important that you get help so your impulses don't get you into serious trouble.

Q: Don't little kids who have ADHD outgrow it by the time they are teens?

A: Often kids with the hyperactive kind of ADHD get less hyperactive as they get into their teens, but usually they still have a lot of difficulty paying attention, remembering what they have read, and getting their work done. They may or may not have other behavior problems. Some kids with ADHD have never been hyperactive at all, but usually their attention problems also continue into their teens.

Q: If I have trouble with homework or tests, do I have ADHD?

A: There could be many reasons why a student struggles with schoolwork and tests. ADHD could be one reason. It may or may not be, but your doctor is the best person to say for sure. Kids with ADHD often say it's hard to concentrate, focus on a task (for example, schoolwork, chores, or a job), manage their time, and finish tasks. This could explain why they may have trouble with schoolwork and tests. Whatever the problem, there are many people willing to help you. You need to find the approach that works best for you.

Q: Does having ADHD mean a person is not very smart?

A: Absolutely not! People who have trouble paying attention may have problems in school, but that doesn't mean they're not smart. In fact, some people with ADHD are very smart, but may not be able to reach their potential in school until they get treatment.

ADHD is a common problem. Teens with ADHD have the potential to do well in school and live a normal life with the right treatment.

Q: Is ADHD more common in boys?

A: More boys than girls are diagnosed with ADHD—about 2 or 3 boys to every 1 girl. However, these numbers do not include the number of girls with the inattentive type of ADHD who are not diagnosed. Girls with the inattentive type of ADHD tend to be overlooked entirely or do not attract attention until they are older.

Q: What do I do if I think I have ADHD?

A: Don't be afraid to talk with your parents or other adults that you trust. Together you can meet with your doctor and find out if you really have ADHD. If you do, your doctor will help you learn how to live with ADHD and find ways to deal with your condition.

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The Diagnosis, Management, and Prevention of Bronchiolitis

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- *Clinical Practice Guideline*
 - *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



CLINICAL PRACTICE GUIDELINE

Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis

abstract

FREE

This guideline is a revision of the clinical practice guideline, “Diagnosis and Management of Bronchiolitis,” published by the American Academy of Pediatrics in 2006. The guideline applies to children from 1 through 23 months of age. Other exclusions are noted. Each key action statement indicates level of evidence, benefit-harm relationship, and level of recommendation. Key action statements are as follows: *Pediatrics* 2014;134:e1474–e1502

DIAGNOSIS

- 1a. Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
- 1b. Clinicians should assess risk factors for severe disease, such as age less than 12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about evaluation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
- 1c. When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

TREATMENT

2. Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
3. Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
- 4a. Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
- 4b. Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak Recommendation [based on randomized controlled trials with inconsistent findings]).

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KEY WORDS

bronchiolitis, infants, children, respiratory syncytial virus, evidence-based, guideline

ABBREVIATIONS

AAP—American Academy of Pediatrics
AOM—acute otitis media
CI—confidence interval
ED—emergency department
KAS—Key Action Statement
LOS—length of stay
MD—mean difference
PCR—polymerase chain reaction
RSV—respiratory syncytial virus
SBI—serious bacterial infection

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Dedicated to the memory of Dr Caroline Breese Hall.

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5. Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).
- 6a. Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low level evidence and reasoning from first principles]).
- 6b. Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).
7. Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
8. Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
9. Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).
- 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
- 10b. Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
- 10c. Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the respiratory syncytial virus season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
- 11a. All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
- 11b. All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).
- 12a. Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).
- 12b. Clinicians should counsel caregivers about exposing the infant or child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong).
13. Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections. (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).
14. Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis. (Evidence Quality: C; observational studies; Recommendation Strength: Moderate Recommendation).

INTRODUCTION

In October 2006, the American Academy of Pediatrics (AAP) published the clinical practice guideline "Diagnosis and Management of Bronchiolitis."¹ The guideline offered recommendations ranked according to level of evidence and the benefit-harm relationship. Since completion of the original evidence review in July 2004, a significant body of literature on bronchiolitis has been published. This update of the 2006 AAP bronchiolitis guideline evaluates published evidence, including that used in the 2006 guideline as well as evidence published since 2004. Key action statements (KASs) based on that evidence are provided.

The goal of this guideline is to provide an evidence-based approach to the diagnosis, management, and prevention of bronchiolitis in children from 1 month through 23 months of age. The guideline is intended for pediatricians, family physicians, emergency medicine specialists, hospitalists, nurse practitioners,

PREVENTION

- 10a. Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of

and physician assistants who care for these children. The guideline does not apply to children with immunodeficiencies, including those with HIV infection or recipients of solid organ or hematopoietic stem cell transplants. Children with underlying respiratory illnesses, such as recurrent wheezing, chronic neonatal lung disease (also known as bronchopulmonary dysplasia), neuromuscular disease, or cystic fibrosis and those with hemodynamically significant congenital heart disease are excluded from the sections on management unless otherwise noted but are included in the discussion of prevention. This guideline will not address long-term sequelae of bronchiolitis, such as recurrent wheezing or risk of asthma, which is a field with a large and distinct literature.

Bronchiolitis is a disorder commonly caused by viral lower respiratory tract infection in infants. Bronchiolitis is characterized by acute inflammation, edema, and necrosis of epithelial cells lining small airways, and increased mucus production. Signs and symptoms typically begin with rhinitis and cough, which may progress to tachypnea, wheezing, rales, use of accessory muscles, and/or nasal flaring.²

Many viruses that infect the respiratory system cause a similar constellation of signs and symptoms. The most common etiology of bronchiolitis is respiratory syncytial virus (RSV), with the highest incidence of infection occurring between December and March in North America; however, regional variations occur³ (Fig 1).⁴ Ninety percent of children are infected with RSV in the first 2 years of life,⁵ and up to 40% will experience lower respiratory tract infection during the initial infection.^{6,7} Infection with RSV does not grant permanent or long-term immunity, with reinfections common throughout life.⁸ Other viruses that cause bronchiolitis include human rhinovirus, human meta-

pneumovirus, influenza, adenovirus, coronavirus, human, and parainfluenza viruses. In a study of inpatients and outpatients with bronchiolitis,⁹ 76% of patients had RSV, 39% had human rhinovirus, 10% had influenza, 2% had coronavirus, 3% had human metapneumovirus, and 1% had parainfluenza viruses (some patients had coinfections, so the total is greater than 100%).

Bronchiolitis is the most common cause of hospitalization among infants during the first 12 months of life. Approximately 100 000 bronchiolitis admissions occur annually in the United States at an estimated cost of \$1.73 billion.¹⁰ One prospective, population-based study sponsored by the Centers for Disease Control and Prevention reported the

average RSV hospitalization rate was 5.2 per 1000 children younger than 24 months of age during the 5-year period between 2000 and 2005.¹¹ The highest age-specific rate of RSV hospitalization occurred among infants between 30 days and 60 days of age (25.9 per 1000 children). For preterm infants (<37 weeks' gestation), the RSV hospitalization rate was 4.6 per 1000 children, a number similar to the RSV hospitalization rate for term infants of 5.2 per 1000. Infants born at <30 weeks' gestation had the highest hospitalization rate at 18.7 children per 1000, although the small number of infants born before 30 weeks' gestation make this number unreliable. Other studies indicate the RSV hospitalization rate in extremely



FIGURE 1

RSV season by US regions. Centers for Disease Control and Prevention. RSV activity—United States, July 2011–Jan 2013. *MMWR Morb Mortal Wkly Rep.* 2013;62(8):141–144.

preterm infants is similar to that of term infants.^{12,13}

METHODS

In June 2013, the AAP convened a new subcommittee to review and revise the 2006 bronchiolitis guideline. The subcommittee included primary care physicians, including general pediatricians, a family physician, and pediatric subspecialists, including hospitalists, pulmonologists, emergency physicians, a neonatologist, and pediatric infectious disease physicians. The subcommittee also included an epidemiologist trained in systematic reviews, a guideline methodologist/informatician, and a parent representative. All panel members reviewed the AAP Policy on Conflict of Interest and Voluntary Disclosure and were given an opportunity to declare any potential conflicts. Any conflicts can be found in the author listing at the end of this guideline. All funding was provided by the AAP, with travel assistance from the American Academy of Family Physicians, the American College of Chest Physicians, the American Thoracic Society, and the American College of Emergency Physicians for their liaisons.

The evidence search and review included electronic database searches in *The Cochrane Library*, Medline via Ovid, and CINAHL via EBSCO. The search strategy is shown in the Appendix. Related article searches were conducted in PubMed. The bibliographies of articles identified by database searches were also reviewed by 1 of 4 members of the committee, and references identified in this manner were added to the review. Articles included in the 2003 evidence report on bronchiolitis in preparation of the AAP 2006 guideline² also were reviewed. In addition, the committee reviewed articles published after completion of the systematic review for these updated guidelines. The current literature re-

view encompasses the period from 2004 through May 2014.

The evidence-based approach to guideline development requires that the evidence in support of a policy be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement "Classifying Recommendations for Clinical Practice"¹⁴ was followed in designating levels of recommendation (Fig 2; Table 1).

A draft version of this clinical practice guideline underwent extensive peer review by committees, councils, and sections within AAP; the American Thoracic Society, American College of Chest Physicians, American Academy

of Family Physicians, and American College of Emergency Physicians; other outside organizations; and other individuals identified by the subcommittee as experts in the field. The resulting comments were reviewed by the subcommittee and, when appropriate, incorporated into the guideline.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with bronchiolitis. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or establish a protocol for the care of all children with bronchiolitis. These recommendations may not provide the only appropriate approach to the management of children with bronchiolitis.

All AAP guidelines are reviewed every 5 years.

AGGREGATE EVIDENCE QUALITY	BENEFIT OR HARM PREDOMINATES	BENEFIT AND HARM BALANCED
LEVEL A Intervention: Well designed and conducted trials, meta-analyses on applicable populations Diagnosis: Independent gold standard studies of applicable populations	STRONG RECOMMENDATION	WEAK RECOMMENDATION (based on balance of benefit and harm)
LEVEL B Trials or diagnostic studies with minor limitations; consistent findings from multiple observational studies	MODERATE RECOMMENDATION	
LEVEL C Single or few observational studies or multiple studies with inconsistent findings or major limitations.	WEAK RECOMMENDATION (based on low quality evidence)	
LEVEL D Expert opinion, case reports, reasoning from first principles		No recommendation may be made.
LEVEL X Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	STRONG RECOMMENDATION MODERATE RECOMMENDATION	

FIGURE 2

Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms leads to designation of a policy as a strong recommendation, moderate recommendation, or weak recommendation.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and quality of evidence is excellent or unobtainable.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and the quality of evidence is good but not excellent (or is unobtainable).	Clinicians would be prudent to follow a moderate recommendation but should remain alert to new information and sensitive to patient preferences.
Weak recommendation (based on low-quality evidence)	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), but the quality of evidence is weak.	Clinicians would be prudent to follow a weak recommendation but should remain alert to new information and very sensitive to patient preferences.
Weak recommendation (based on balance of benefits and harms)	Weak recommendation is provided when the aggregate database shows evidence of both benefit and harm that appear similar in magnitude for any available courses of action	Clinicians should consider the options in their decision making, but patient preference may have a substantial role.

DIAGNOSIS

Key Action Statement 1a

Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 1a

Aggregate evidence quality	B
Benefits	Inexpensive, noninvasive, accurate
Risk, harm, cost	Missing other diagnoses
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Key Action Statement 1b

Clinicians should assess risk factors for severe disease, such as age <12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about eval-

uation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 1b

Aggregate evidence quality	B
Benefits	Improved ability to predict course of illness, appropriate disposition
Risk, harm, cost	Possible unnecessary hospitalization parental anxiety
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	"Assess" is not defined
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 1c

When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 1b

Aggregate evidence quality	B
Benefits	Decreased radiation exposure, noninvasive (less procedure-associated discomfort), decreased antibiotic use, cost savings, time saving
Risk, harm, cost	Misdiagnosis, missed diagnosis of comorbid condition
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Infants and children with unexpected worsening disease
Strength	Moderate recommendation
Differences of opinion	None

The main goals in the history and physical examination of infants presenting with wheeze or other lower respiratory tract symptoms, particularly in the winter season, is to differentiate infants with probable viral bronchiolitis from those with other disorders. In addition, an estimate of disease severity (increased respiratory rate, retractions, decreased oxygen saturation) should

be made. Most clinicians recognize bronchiolitis as a constellation of clinical signs and symptoms occurring in children younger than 2 years, including a viral upper respiratory tract prodrome followed by increased respiratory effort and wheezing. Clinical signs and symptoms of bronchiolitis consist of rhinorrhea, cough, tachypnea, wheezing, rales, and increased respiratory effort manifested as grunting, nasal flaring, and intercostal and/or subcostal retractions.

The course of bronchiolitis is variable and dynamic, ranging from transient events, such as apnea, to progressive respiratory distress from lower airway obstruction. Important issues to assess in the history include the effects of respiratory symptoms on mental status, feeding, and hydration. The clinician should assess the ability of the family to care for the child and to return for further evaluation if needed. History of underlying conditions, such as prematurity, cardiac disease, chronic pulmonary disease, immunodeficiency, or episodes of previous wheezing, should be identified. Underlying conditions that may be associated with an increased risk of progression to severe disease or mortality include hemodynamically significant congenital heart disease, chronic lung disease (bronchopulmonary dysplasia), congenital anomalies,^{15–17} in utero smoke exposure,¹⁸ and the presence of an immunocompromising state.^{19,20} In addition, genetic abnormalities have been associated with more severe presentation with bronchiolitis.²¹ Assessment of a child with bronchiolitis, including the physical examination, can be complicated by variability in the disease state and may require serial observations over time to fully assess the child's status. Upper airway obstruction contributes to work of breathing. Suctioning and positioning may decrease the work of breathing and improve the quality of the examination. Respiratory

rate in otherwise healthy children changes considerably over the first year of life.^{22–25} In hospitalized children, the 50th percentile for respiratory rate decreased from 41 at 0 to 3 months of age to 31 at 12 to 18 months of age.²⁶ Counting respiratory rate over the course of 1 minute is more accurate than shorter observations.²⁷ The presence of a normal respiratory rate suggests that risk of significant viral or bacterial lower respiratory tract infection or pneumonia in an infant is low (negative likelihood ratio approximately 0.5),^{27–29} but the presence of tachypnea does not distinguish between viral and bacterial disease.^{30,31}

The evidence relating the presence of specific findings in the assessment of bronchiolitis to clinical outcomes is limited. Most studies addressing this issue have enrolled children when presenting to hospital settings, including a large, prospective, multicenter study that assessed a variety of outcomes from the emergency department (ED) and varied inpatient settings.^{18,32,33} Severe adverse events, such as ICU admission and need for mechanical ventilation, are uncommon among children with bronchiolitis and limit the power of these studies to detect clinically important risk factors associated with disease progression.^{16,34,35} Tachypnea, defined as a respiratory rate ≥ 70 per minute, has been associated with increased risk of severe disease in some studies^{35–37} but not others.³⁸ Many scoring systems have been developed in an attempt to objectively quantify respiratory distress, although none has achieved widespread acceptance and few have demonstrated any predictive validity, likely because of the substantial temporal variability in physical findings in infants with bronchiolitis.³⁹

Pulse oximetry has been rapidly adopted into clinical assessment of children with bronchiolitis on the basis of data

suggesting that it reliably detects hypoxemia not suspected on physical examination^{36,40}; however, few studies have assessed the effectiveness of pulse oximetry to predict clinical outcomes. Among inpatients, perceived need for supplemental oxygen on the basis of pulse oximetry has been associated with prolonged hospitalization, ICU admission, and mechanical ventilation.^{16,34,41} Among outpatients, available evidence differs on whether mild reductions in pulse oximetry (<95% on room air) predict progression of disease or need for a return observational visit.³⁸

Apnea has been reported to occur with a wide range of prevalence estimates and viral etiologies.^{42,43} Retrospective, hospital-based studies have included a high proportion of infants with risk factors, such as prematurity or neuromuscular disease, that may have biased the prevalence estimates. One large study found no apnea events for infants assessed as low risk by using several risk factors: age >1 month for full-term infants or 48 weeks' postconceptional age for preterm infants, and absence of any previous apneic event at presentation to the hospital.⁴⁴ Another large multicenter study found no association between the specific viral agent and risk of apnea in bronchiolitis.⁴²

The literature on viral testing for bronchiolitis has expanded in recent years with the availability of sensitive polymerase chain reaction (PCR) assays. Large studies of infants hospitalized for bronchiolitis have consistently found that 60% to 75% have positive test results for RSV, and have noted coinfections in up to one-third of infants.^{32,33,45} In the event an infant receiving monthly prophylaxis is hospitalized with bronchiolitis, testing should be performed to determine if RSV is the etiologic agent. If a breakthrough RSV infection is determined to be present based on antigen detection or other

assay, monthly palivizumab prophylaxis should be discontinued because of the very low likelihood of a second RSV infection in the same year. Apart from this setting, routine virologic testing is not recommended.

Infants with non-RSV bronchiolitis, in particular human rhinovirus, appear to have a shorter courses and may represent a different phenotype associated with repeated wheezing.³² PCR assay results should be interpreted cautiously, given that the assay may detect prolonged viral shedding from an unrelated previous illness, particularly with rhinovirus. In contrast, RSV detected by PCR assay almost always is associated with disease. At the individual patient level, the value of identifying a specific viral etiology causing bronchiolitis has not been demonstrated.³³

Current evidence does not support routine chest radiography in children with bronchiolitis. Although many infants with bronchiolitis have abnormalities on chest radiography, data are insufficient to demonstrate that chest radiography correlates well with disease severity. Atelectasis on chest radiography was associated with increased risk of severe disease in 1 outpatient study.¹⁶ Further studies, including 1 randomized trial, suggest children with suspected lower respiratory tract infection who had radiography performed were more likely to receive antibiotics without any difference in outcomes.^{46,47} Initial radiography should be reserved for cases in which respiratory effort is severe enough to warrant ICU admission or where signs of an airway complication (such as pneumothorax) are present.

TREATMENT

ALBUTEROL

Key Action Statement 2

Clinicians should not administer albuterol (or salbutamol) to infants

and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 2

Aggregate evidence quality	B
Benefits	Avoid adverse effects, avoid ongoing use of ineffective medication, lower costs
Risk, harm, cost	Missing transient benefit of drug
Benefit-harm assessment	Benefits outweigh harms
Value judgments	Overall ineffectiveness outweighs possible transient benefit
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None
Notes	This guideline no longer recommends a trial of albuterol, as was considered in the 2006 AAP bronchiolitis guideline

Although several studies and reviews have evaluated the use of bronchodilator medications for viral bronchiolitis, most randomized controlled trials have failed to demonstrate a consistent benefit from α - or β -adrenergic agents. Several meta-analyses and systematic reviews^{48–53} have shown that bronchodilators may improve clinical symptom scores, but they do not affect disease resolution, need for hospitalization, or length of stay (LOS). Because clinical scores may vary from one observer to the next^{39,54} and do not correlate with more objective measures, such as pulmonary function tests,⁵⁵ clinical scores are not validated measures of the efficacy of bronchodilators. Although transient improvements in clinical score have been observed, most infants treated with bronchodilators will not benefit from their use.

A recently updated Cochrane systematic review assessing the impact of bronchodilators on oxygen saturation, the primary outcome measure, reported 30 randomized controlled trials involving 1992 infants in 12 countries.⁵⁶ Some studies included in this review evaluated agents other than albuterol/salbutamol (eg, ipratropium and meta-proterenol) but did not include epinephrine. Small sample sizes, lack of standardized methods for outcome evaluation (eg, timing of assessments), and lack of standardized intervention (various bronchodilators, drug dosages, routes of administration, and nebulization delivery systems) limit the interpretation of these studies. Because of variable study designs as well as the inclusion of infants who had a history of previous wheezing in some studies, there was considerable heterogeneity in the studies. Sensitivity analysis (ie, including only studies at low risk of bias) significantly reduced heterogeneity measures for oximetry while having little effect on the overall effect size of oximetry (mean difference [MD] -0.38 , 95% confidence interval [CI] -0.75 to 0.00). Those studies showing benefit^{57–59} are methodologically weaker than other studies and include older children with recurrent wheezing. Results of the Cochrane review indicated no benefit in the clinical course of infants with bronchiolitis who received bronchodilators. The potential adverse effects (tachycardia and tremors) and cost of these agents outweigh any potential benefits.

In the previous iteration of this guideline, a trial of β -agonists was included as an option. However, given the greater strength of the evidence demonstrating no benefit, and that there is no well-established way to determine an “objective method of response” to bronchodilators in bronchiolitis, this option has been removed. Although it is true that a small subset of children

with bronchiolitis may have reversible airway obstruction resulting from smooth muscle constriction, attempts to define a subgroup of responders have not been successful to date. If a clinical trial of bronchodilators is undertaken, clinicians should note that the variability of the disease process, the host's airway, and the clinical assessments, particularly scoring, would limit the clinician's ability to observe a clinically relevant response to bronchodilators.

Chavasse et al⁶⁰ reviewed the available literature on use of β -agonists for children younger than 2 years with recurrent wheezing. At the time of that review, there were 3 studies in the outpatient setting, 2 in the ED, and 3 in the pulmonary function laboratory setting. This review concluded there were no clear benefits from the use of β -agonists in this population. The authors noted some conflicting evidence, but further study was recommended only if the population could be clearly defined and meaningful outcome measures could be identified.

The population of children with bronchiolitis studied in most trials of bronchodilators limits the ability to make recommendations for all clinical scenarios. Children with severe disease or with respiratory failure were generally excluded from these trials, and this evidence cannot be generalized to these situations. Studies using pulmonary function tests show no effect of albuterol among infants hospitalized with bronchiolitis.^{56,61} One study in a critical care setting showed a small decrease in inspiratory resistance after albuterol in one group and levalbuterol in another group, but therapy was accompanied by clinically significant tachycardia.⁶² This small clinical change occurring with significant adverse effects does not justify recommending albuterol for routine care.

EPINEPHRINE

Key Action Statement 3

Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 3

Aggregate evidence quality	B
Benefits	Avoiding adverse effects, lower costs, avoiding ongoing use of ineffective medication
Risk, harm, cost	Missing transient benefit of drug
Benefit-harm assessment	Benefits outweigh harms
Value judgments	The overall ineffectiveness outweighs possible transient benefit
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Rescue treatment of rapidly deteriorating patients
Strength	Strong recommendation
Differences of opinion	None

Epinephrine is an adrenergic agent with both β - and α -receptor agonist activity that has been used to treat upper and lower respiratory tract illnesses both as a systemic agent and directly into the respiratory tract, where it is typically administered as a nebulized solution. Nebulized epinephrine has been administered in the racemic form and as the purified L-enantiomer, which is commercially available in the United States for intravenous use. Studies in other diseases, such as croup, have found no difference in efficacy on the basis of preparation,⁶³ although the comparison has not been specifically studied for bronchiolitis. Most studies have compared L-epinephrine to placebo or albuterol. A recent Cochrane meta-

analysis by Hartling et al⁶⁴ systematically evaluated the evidence on this topic and found no evidence for utility in the inpatient setting. Two large, multicenter randomized trials comparing nebulized epinephrine to placebo⁶⁵ or albuterol⁶⁶ in the hospital setting found no improvement in LOS or other inpatient outcomes. A recent, large multicenter trial found a similar lack of efficacy compared with placebo and further demonstrated longer LOS when epinephrine was used on a fixed schedule compared with an as-needed schedule.⁶⁷ This evidence suggests epinephrine should not be used in children hospitalized for bronchiolitis, except potentially as a rescue agent in severe disease, although formal study is needed before a recommendation for the use of epinephrine in this setting.

The role of epinephrine in the outpatient setting remains controversial. A major addition to the evidence base came from the Canadian Bronchiolitis Epinephrine Steroid Trial.⁶⁸ This multicenter randomized trial enrolled 800 patients with bronchiolitis from 8 EDs and compared hospitalization rates over a 7-day period. This study had 4 arms: nebulized epinephrine plus oral dexamethasone, nebulized epinephrine plus oral placebo, nebulized placebo plus oral dexamethasone, and nebulized placebo plus oral placebo. The group of patients who received epinephrine concomitantly with corticosteroids had a lower likelihood of hospitalization by day 7 than the double placebo group, although this effect was no longer statistically significant after adjusting for multiple comparisons.

The systematic review by Hartling et al⁶⁴ concluded that epinephrine reduced hospitalizations compared with placebo on the day of the ED visit but not overall. Given that epinephrine

has a transient effect and home administration is not routine practice, discharging an infant after observing a response in a monitored setting raises concerns for subsequent progression of illness. Studies have not found a difference in revisit rates, although the numbers of revisits are small and may not be adequately powered for this outcome. In summary, the current state of evidence does not support a routine role for epinephrine for bronchiolitis in outpatients, although further data may help to better define this question.

HYPERTONIC SALINE

Key Action Statement 4a

Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 4a

Aggregate evidence quality	B
Benefits	Avoiding adverse effects, such as wheezing and excess secretions, cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 4b

Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak

Recommendation [based on randomized controlled trials with inconsistent findings]).

Action Statement Profile KAS 4b

Aggregate evidence quality	B
Benefits	May shorten hospital stay if LOS is >72 h
Risk, harm, cost	Adverse effects such as wheezing and excess secretions; cost
Benefit-harm assessment	Benefits outweigh harms for longer hospital stays
Value judgments	Anticipating an individual child's LOS is difficult. Most US hospitals report an average LOS of <72 h for patients with bronchiolitis. This weak recommendation applies only if the average length of stay is >72 h
Intentional vagueness	This weak recommendation is based on an average LOS and does not address the individual patient.
Role of patient preferences	None
Exclusions	None
Strength	Weak
Differences of opinion	None

Nebulized hypertonic saline is an increasingly studied therapy for acute viral bronchiolitis. Physiologic evidence suggests that hypertonic saline increases mucociliary clearance in both normal and diseased lungs.^{69–71} Because the pathology in bronchiolitis involves airway inflammation and resultant mucus plugging, improved mucociliary clearance should be beneficial, although there is only indirect evidence to support such an assertion. A more specific theoretical mechanism of action has been proposed on the basis of the concept of rehydration of the airway surface liquid, although again, evidence remains indirect.⁷²

A 2013 Cochrane review⁷³ included 11 trials involving 1090 infants with mild to moderate disease in both inpatient and emergency settings. There were 6 studies involving 500 inpatients providing data

for the analysis of LOS with an aggregate 1-day decrease reported, a result largely driven by the inclusion of 3 studies with relatively long mean length of stay of 5 to 6 days. The analysis of effect on clinical scores included 7 studies involving 640 patients in both inpatient and outpatient settings and demonstrated incremental positive effect with each day posttreatment from day 1 to day 3 (−0.88 MD on day 1, −1.32 MD on day 2, and −1.51 MD on day 3). Finally, Zhang et al⁷³ found no effect on hospitalization rates in the pooled analysis of 1 outpatient and 3 ED studies including 380 total patients.

Several randomized trials published after the Cochrane review period further informed the current guideline recommendation. Four trials evaluated admission rates from the ED, 3 using 3% saline and 1 using 7% saline.^{74–76} A single trial⁷⁶ demonstrated a difference in admission rates from the ED favoring hypertonic saline, although the other 4 studies were concordant with the studies included in the Cochrane review. However, contrary to the studies included in the Cochrane review, none of the more recent trials reported improvement in LOS and, when added to the older studies for an updated meta-analysis, they significantly attenuate the summary estimate of the effect on LOS.^{76,77} Most of the trials included in the Cochrane review occurred in settings with typical LOS of more than 3 days in their usual care arms. Hence, the significant decrease in LOS noted by Zhang et al⁷³ may not be generalizable to the United States where the average LOS is 2.4 days.¹⁰ One other ongoing clinical trial performed in the United States, unpublished except in abstract form, further supports the observation that hypertonic saline does not decrease LOS in settings where expected stays are less than 3 days.⁷⁸

The preponderance of the evidence suggests that 3% saline is safe and effective at improving symptoms of mild to moderate bronchiolitis after 24 hours of use and reducing hospital LOS in settings in which

the duration of stay typically exceeds 3 days. It has not been shown to be effective at reducing hospitalization in emergency settings or in areas where the length of usage is brief. It has not been studied in intensive care settings, and most trials have included only patients with mild to moderate disease. Most studies have used a 3% saline concentration, and most have combined it with bronchodilators with each dose; however, there is retrospective evidence that the rate of adverse events is similar without bronchodilators,⁷⁹ as well as prospective evidence extrapolated from 2 trials without bronchodilators.^{79,80} A single study was performed in the ambulatory outpatient setting⁸¹; however, future studies in the United States should focus on sustained usage on the basis of pattern of effects discerned in the available literature.

CORTICOSTEROIDS

Key Action Statement 5

Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 5

Aggregate evidence quality	A
Benefits	No clinical benefit, avoiding adverse effects
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Although there is good evidence of benefit from corticosteroids in other

respiratory diseases, such as asthma and croup,^{82–84} the evidence on corticosteroid use in bronchiolitis is negative. The most recent Cochrane systematic review shows that corticosteroids do not significantly reduce outpatient admissions when compared with placebo (pooled risk ratio, 0.92; 95% CI, 0.78 to 1.08; and risk ratio, 0.86; 95% CI, 0.7 to 1.06, respectively) and do not reduce LOS for inpatients (MD –0.18 days; 95% CI –0.39 to 0.04).⁸⁵ No other comparisons showed relevant differences for either primary or secondary outcomes. This review contained 17 trials with 2596 participants and included 2 large ED-based randomized trials, neither of which showed reductions in hospital admissions with treatment with corticosteroids as compared with placebo.^{69,86}

One of these large trials, the Canadian Bronchiolitis Epinephrine Steroid Trial, however, did show a reduction in hospitalizations 7 days after treatment with combined nebulized epinephrine and oral dexamethasone as compared with placebo.⁶⁹ Although an unadjusted analysis showed a relative risk for hospitalization of 0.65 (95% CI 0.45 to 0.95; $P = .02$) for combination therapy as compared with placebo, adjustment for multiple comparison rendered the result insignificant ($P = .07$). These results have generated considerable controversy.⁸⁷ Although there is no standard recognized rationale for why combination epinephrine and dexamethasone would be synergistic in infants with bronchiolitis, evidence in adults and children older than 6 years with asthma shows that adding inhaled long-acting β agonists to moderate/high doses of inhaled corticosteroids allows reduction of the corticosteroid dose by, on average, 60%.⁸⁸ Basic science studies focused on understanding the interaction between β agonists and corticosteroids have shown potential mechanisms for

why simultaneous administration of these drugs could be synergistic.^{89–92} However, other bronchiolitis trials of corticosteroids administered by using fixed simultaneous bronchodilator regimens have not consistently shown benefit^{93–97}; hence, a recommendation regarding the benefit of combined dexamethasone and epinephrine therapy is premature.

The systematic review of corticosteroids in children with bronchiolitis cited previously did not find any differences in short-term adverse events as compared with placebo.⁸⁶ However, corticosteroid therapy may prolong viral shedding in patients with bronchiolitis.¹⁷

In summary, a comprehensive systematic review and large multicenter randomized trials provide clear evidence that corticosteroids alone do not provide significant benefit to children with bronchiolitis. Evidence for potential benefit of combined corticosteroid and agents with both α - and β -agonist activity is at best tentative, and additional large trials are needed to clarify whether this therapy is effective.

Further, although there is no evidence of short-term adverse effects from corticosteroid therapy, other than prolonged viral shedding, in infants and children with bronchiolitis, there is inadequate evidence to be certain of safety.

OXYGEN

Key Action Statement 6a

Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).

Action Statement Profile KAS 6a

Benefits	Decreased hospitalizations, decreased LOS
Risk, harm, cost	Hypoxemia, physiologic stress, prolonged LOS, increased hospitalizations, increased LOS, cost
Benefit-harm assessment	Benefits outweigh harms
Value judgments	Oxyhemoglobin saturation >89% is adequate to oxygenate tissues; the risk of hypoxemia with oxyhemoglobin saturation >89% is minimal
Intentional vagueness	None
Role of patient preferences	Limited
Exclusions	Children with acidosis or fever
Strength	Weak recommendation (based on low-level evidence/reasoning from first principles)
Differences of opinion	None

Key Action Statement 6b

Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: C; Recommendation Strength: Weak Recommendation [based on lower-level evidence]).

Action Statement Profile KAS 6b

Aggregate evidence quality	C
Benefits	Shorter LOS, decreased alarm fatigue, decreased cost
Risk, harm, cost	Delayed detection of hypoxemia, delay in appropriate weaning of oxygen
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Limited
Exclusions	None
Strength	Weak recommendation (based on lower level of evidence)
Differences of opinion	None

Although oxygen saturation is a poor predictor of respiratory distress, it is

associated closely with a perceived need for hospitalization in infants with bronchiolitis.^{98,99} Additionally, oxygen saturation has been implicated as a primary determinant of LOS in bronchiolitis.^{40,100,101}

Physiologic data based on the oxyhemoglobin dissociation curve (Fig 3) demonstrate that small increases in arterial partial pressure of oxygen are associated with marked improvement in pulse oxygen saturation when the latter is less than 90%; with pulse oxygen saturation readings greater than 90% it takes very large elevations in arterial partial pressure of oxygen to affect further increases. In infants and children with bronchiolitis, no data exist to suggest such increases result in any clinically significant difference in physiologic function, patient symptoms, or clinical outcomes. Although it is well understood that acidosis, temperature, and 2,3-diphosphoglutarate influence the oxyhemoglobin dissociation curve, there has never been research to demonstrate how those influences practically affect infants with hypoxemia. The risk of hypoxemia must be weighed against the risk of hospitalization when making any decisions about site of care. One study of hospitalized children with bronchiolitis, for example, noted a 10% adverse error or near-miss rate for harm-causing interventions.¹⁰³ There are no studies on the effect of short-term, brief periods of hypoxemia such as may be seen in bronchiolitis. Transient hypoxemia is common in healthy infants.¹⁰⁴ Travel of healthy children even to moderate altitudes of 1300 m results in transient sleep desaturation to an average of 84% with no known adverse consequences.¹⁰⁵ Although children with chronic hypoxemia do incur developmental and behavioral problems, children who suffer intermittent hypoxemia from diseases such as asthma

do not have impaired intellectual abilities or behavioral disturbance.^{106–108}

Supplemental oxygen provided for infants not requiring additional respiratory support is best initiated with nasal prongs, although exact measurement of fraction of inspired oxygen is unreliable with this method.¹⁰⁹

Pulse oximetry is a convenient method to assess the percentage of hemoglobin bound by oxygen in children. Pulse oximetry has been erroneously used in bronchiolitis as a proxy for respiratory distress. Accuracy of pulse oximetry is poor, especially in the 76% to 90% range.¹¹⁰ Further, it has been well demonstrated that oxygen saturation has much less impact on respiratory drive than carbon dioxide concentrations in the blood.¹¹¹ There is very poor correlation between respiratory distress and oxygen saturations among infants with lower respiratory tract infections.¹¹² Other than cyanosis, no published clinical sign, model, or score accurately identifies hypoxemic children.¹¹³

Among children admitted for bronchiolitis, continuous pulse oximetry measurement is not well studied and potentially problematic for children who do not require oxygen. Transient desaturation is a normal phenomenon in healthy infants. In 1 study of 64 healthy infants between 2 weeks and 6 months of age, 60% of these infants exhibited a transient oxygen desaturation below 90%, to values as low as 83%.¹⁰⁵ A retrospective study of the role of continuous measurement of oxygenation in infants hospitalized with bronchiolitis found that 1 in 4 patients incur unnecessarily prolonged hospitalization as a result of a perceived need for oxygen outside of other symptoms⁴⁰ and no evidence of benefit was found.

Pulse oximetry is prone to errors of measurement. Families of infants hospitalized with continuous pulse oximeters are exposed to frequent alarms that

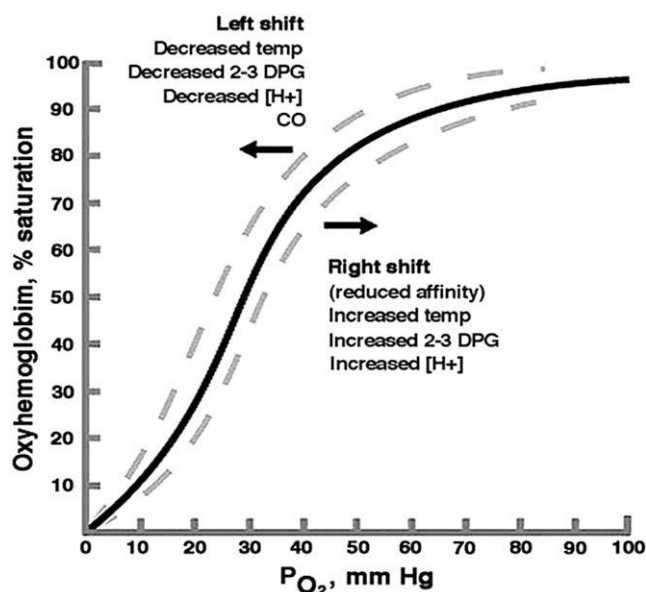


FIGURE 3

Oxyhemoglobin dissociation curve showing percent saturation of hemoglobin at various partial pressures of oxygen (reproduced with permission from the educational Web site www.anaesthesiak.com).¹⁰²

may negatively affect sleep. Alarm fatigue is recognized by The Joint Commission as a contributor toward in-hospital morbidity and mortality.¹¹⁴ One adult study demonstrated very poor documentation of hypoxemia alerts by pulse oximetry, an indicator of alarm fatigue.¹¹⁵ Pulse oximetry probes can fall off easily, leading to inaccurate measurements and alarms.¹¹⁶ False reliance on pulse oximetry may lead to less careful monitoring of respiratory status. In one study, continuous pulse oximetry was associated with increased risk of minor adverse events in infants admitted to a general ward.¹¹⁷ The pulse oximetry-monitored patients were found to have less-effective surveillance of their severity of illness when controlling for other variables.

There are a number of new approaches to oxygen delivery in bronchiolitis, 2 of which are home oxygen and high-frequency nasal cannula. There is emerging evidence for the role of home oxygen in reducing LOS or admission rate for infants with bronchiolitis, in-

cluding 2 randomized trials.^{118,119} Most of the studies have been performed in areas of higher altitude, where prolonged hypoxemia is a prime determinant of LOS in the hospital.^{120,121} Readmission rates may be moderately higher in patients discharged with home oxygen; however, overall hospital use may be reduced,¹²² although not in all settings.¹²³ Concerns have been raised that home pulse oximetry may complicate care or confuse families.¹²⁴ Communication with follow-up physicians is important, because primary care physicians may have difficulty determining safe pulse oximetry levels for discontinuation of oxygen.¹²⁵ Additionally, there may be an increased demand for follow-up outpatient visits associated with home oxygen use.¹²⁴

Use of humidified, heated, high-flow nasal cannula to deliver air-oxygen mixtures provides assistance to infants with bronchiolitis through multiple proposed mechanisms.¹²⁶ There is evidence that high-flow nasal cannula improves physiologic measures of respiratory effort and can generate

continuous positive airway pressure in bronchiolitis.^{127–130} Clinical evidence suggests it reduces work of breathing^{131,132} and may decrease need for intubation,^{133–136} although studies are generally retrospective and small. The therapy has been studied in the ED^{136,137} and the general inpatient setting,^{134,138} as well as the ICU. The largest and most rigorous retrospective study to date was from Australia,¹³⁸ which showed a decline in intubation rate in the subgroup of infants with bronchiolitis ($n = 330$) from 37% to 7% after the introduction of high-flow nasal cannula, while the national registry intubation rate remained at 28%. A single pilot for a randomized trial has been published to date.¹³⁹ Although promising, the absence of any completed randomized trial of the efficacy of high-flow nasal cannula in bronchiolitis precludes specific recommendations on its use at present. Pneumothorax is a reported complication.

CHEST PHYSIOTHERAPY

Key Action Statement 7

Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 7

Aggregate evidence quality	B
Benefits	Decreased stress from therapy, reduced cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Airway edema, sloughing of respiratory epithelium into airways, and generalized hyperinflation of the lungs, coupled with poorly developed collateral ventilation, put infants with bronchiolitis at risk for atelectasis. Although lobar atelectasis is not characteristic of this disease, chest radiographs may show evidence of subsegmental atelectasis, prompting clinicians to consider ordering chest physiotherapy to promote airway clearance. A Cochrane Review¹⁴⁰ found 9 randomized controlled trials that evaluated chest physiotherapy in hospitalized patients with bronchiolitis. No clinical benefit was found by using vibration or percussion (5 trials)^{141–144} or passive expiratory techniques (4 trials).^{145–148} Since that review, a study¹⁴⁹ of the passive expiratory technique found a small, but significant reduction in duration of oxygen therapy, but no other benefits.

Suctioning of the nasopharynx to remove secretions is a frequent practice in infants with bronchiolitis. Although suctioning the nares may provide temporary relief of nasal congestion or upper airway obstruction, a retrospective study reported that deep suctioning¹⁵⁰ was associated with longer LOS in hospitalized infants 2 to 12 months of age. The same study also noted that lapses of greater than 4 hours in noninvasive, external nasal suctioning were also associated with longer LOS. Currently, there are insufficient data to make a recommendation about suctioning, but it appears that routine use of “deep” suctioning^{151,153} may not be beneficial.

ANTIBACTERIALS

Key Action Statement 8

Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one. (Evidence

Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 8

Aggregate evidence quality	B
Benefits	Fewer adverse effects, less resistance to antibacterial agents, lower cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	Strong suspicion is not specifically defined and requires clinician judgment. An evaluation for the source of possible serious bacterial infection should be completed before antibiotic use
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Infants with bronchiolitis frequently receive antibacterial therapy because of fever,¹⁵² young age,¹⁵³ and concern for secondary bacterial infection.¹⁵⁴ Early randomized controlled trials^{155,156} showed no benefit from routine antibacterial therapy for children with bronchiolitis. Nonetheless, antibiotic therapy continues to be overused in young infants with bronchiolitis because of concern for an undetected bacterial infection. Studies have shown that febrile infants without an identifiable source of fever have a risk of bacteremia that may be as high as 7%. However, a child with a distinct viral syndrome, such as bronchiolitis, has a lower risk (much less than 1%) of bacterial infection of the cerebrospinal fluid or blood.¹⁵⁷

Ralston et al¹⁵⁸ conducted a systematic review of serious bacterial infections (SBIs) occurring in hospitalized febrile infants between 30 and 90 days of age with bronchiolitis. Instances of bacteremia or meningitis were extremely rare.

Enteritis was not evaluated. Urinary tract infection occurred at a rate of approximately 1%, but asymptomatic bacteriuria may have explained this finding. The authors concluded routine screening for SBI among hospitalized febrile infants with bronchiolitis between 30 and 90 days of age is not justified. Limited data suggest the risk of bacterial infection in hospitalized infants with bronchiolitis younger than 30 days of age is similar to the risk in older infants. An abnormal white blood cell count is not useful for predicting a concurrent SBI in infants and young children hospitalized with RSV lower respiratory tract infection.¹⁵⁹ Several retrospective studies support this conclusion.^{160–166} Four prospective studies of SBI in patients with bronchiolitis and/or RSV infections also demonstrated low rates of SBI.^{167–171}

Approximately 25% of hospitalized infants with bronchiolitis have radiographic evidence of atelectasis, and it may be difficult to distinguish between atelectasis and bacterial infiltrate or consolidation.¹⁶⁹ Bacterial pneumonia in infants with bronchiolitis without consolidation is unusual.¹⁷⁰ Antibiotic therapy may be justified in some children with bronchiolitis who require intubation and mechanical ventilation for respiratory failure.^{172,173}

Although acute otitis media (AOM) in infants with bronchiolitis may be attributable to viruses, clinical features generally do not permit differentiation of viral AOM from those with a bacterial component.¹⁷⁴ Two studies address the frequency of AOM in patients with bronchiolitis. Andrade et al¹⁷⁵ prospectively identified AOM in 62% of 42 patients who presented with bronchiolitis. AOM was present in 50% on entry to the study and developed in an additional 12% within 10 days. A subsequent report¹⁷⁶ followed 150 children hospitalized for bronchiolitis for the development of AOM. Seventy-nine (53%) developed AOM, two-thirds within the

first 2 days of hospitalization. AOM did not influence the clinical course or laboratory findings of bronchiolitis. The current AAP guideline on AOM¹⁷⁷ recommends that a diagnosis of AOM should include bulging of the tympanic membrane. This is based on bulging being the best indicator for the presence of bacteria in multiple tympanocentesis studies and on 2 articles comparing antibiotic to placebo therapy that used a bulging tympanic membrane as a necessary part of the diagnosis.^{178,179} New studies are needed to determine the incidence of AOM in bronchiolitis by using the new criterion of bulging of the tympanic membrane. Refer to the AOM guideline¹⁸⁰ for recommendations regarding the management of AOM.

NUTRITION AND HYDRATION

Key Action Statement 9

Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 9

Aggregate evidence quality	X
Benefits	Maintaining hydration
Risk, harm, cost	Risk of infection, risk of aspiration with nasogastric tube, discomfort, hyponatremia, intravenous infiltration, overhydration
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Shared decision as to which mode is used
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

The level of respiratory distress attributable to bronchiolitis guides the indications for fluid replacement. Conversely, food intake in the previous 24 hours may be a predictor of oxygen saturation among infants with bron-

chiolitis. One study found that food intake at less than 50% of normal for the previous 24 hours is associated with a pulse oximetry value of <95%.¹⁸⁰ Infants with mild respiratory distress may require only observation, particularly if feeding remains unaffected. When the respiratory rate exceeds 60 to 70 breaths per minute, feeding may be compromised, particularly if nasal secretions are copious. There is limited evidence to suggest coordination of breathing with swallowing may be impaired among infants with bronchiolitis.¹⁸¹ These infants may develop increased nasal flaring, retractions, and prolonged expiratory wheezing when fed and may be at increased risk of aspiration.¹⁸²

One study estimated that one-third of infants hospitalized for bronchiolitis require fluid replacement.¹⁸³ One case series¹⁸⁴ and 2 randomized trials,^{185,186} examined the comparative efficacy and safety of the intravenous and nasogastric routes for fluid replacement. A pilot trial in Israel that included 51 infants younger than 6 months demonstrated no significant differences in the duration of oxygen needed or time to full oral feeds between

significant. In a larger open randomized trial including infants between 2 and 12 months of age and conducted in Australia and New Zealand, there were no significant differences in rates of admission to ICUs, need for ventilatory support, and adverse events between 381 infants assigned to nasogastric hydration and 378 infants assigned to intravenous hydration.¹⁸⁸ There was a difference of 4 hours in mean LOS between the intravenous group (82.2 hours) and the nasogastric group (86.2 hours) that was not statistically significant. The nasogastric route had a higher success rate of insertion than the intravenous route. Parental satisfaction scores did not differ between the intravenous and nasogastric groups. These studies suggest that infants who have difficulty feeding safely because of respiratory distress can receive either intravenous or nasogastric fluid replacement; however, more evidence is needed to increase the strength of this recommendation.

The possibility of fluid retention related to production of antidiuretic hormone has been raised in patients with bronchiolitis.^{187–189} Therefore, receipt of hypotonic fluid replacement and maintenance fluids may increase the risk of iatrogenic hyponatremia in these infants. A recent meta-analysis demonstrated that among hospitalized children requiring maintenance fluids, the use of hypotonic fluids was associated with significant hyponatremia compared with isotonic fluids in older children.¹⁹⁰ Use of isotonic fluids, in general, appears to be safer.

PREVENTION

Key Action Statement 10a

Clinicians should not administer palivizumab to otherwise healthy

infants receiving intravenous 5% dextrose in normal saline solution or nasogastric breast milk or formula.¹⁸⁷ Infants in the intravenous group had a shorter LOS (100 vs 120 hours) but it was not statistically

infants with a gestational age of 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 10a

Aggregate evidence quality	B
Benefits	Reduced pain of injections, reduced use of a medication that has shown minimal benefit, reduced adverse effects, reduced visits to health care provider with less exposure to illness
Risk, harm, cost	Minimal increase in risk of RSV hospitalization
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to not accept palivizumab
Exclusions	Infants with chronic lung disease of prematurity and hemodynamically significant cardiac disease (as described in KAS 10b)
Strength	Recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab

Key Action Statement 10b

Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks, 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 10b

Aggregate evidence quality	B
Benefits	Reduced risk of RSV hospitalization
Risk, harm, cost	Injection pain; increased risk of illness from increased visits to clinician office or clinic; cost; side effects from palivizumab
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to not accept palivizumab
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab ^{191,192}

Key Action Statement 10c

Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the RSV season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B, Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 10c

Aggregate evidence quality	B
Benefits	Reduced risk of hospitalization; reduced admission to ICU
Risk, harm, cost	Injection pain; increased risk of illness from increased visits to clinician office or clinic; cost; adverse effects of palivizumab
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Fewer doses should be used if the bronchiolitis season ends before the completion of 5 doses; if the child is hospitalized with a breakthrough RSV, monthly prophylaxis should be discontinued
Strength	Moderate recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab ^{191,192}

Detailed evidence to support the policy statement on palivizumab and this palivizumab section can be found in the technical report on palivizumab.¹⁹²

Palivizumab was licensed by the US Food and Drug Administration in June 1998 largely on the basis of results of 1 clinical trial.¹⁹³ The results of a second clinical trial among children with congenital heart disease were reported in December 2003.¹⁹⁴ No other prospective, randomized, placebo-controlled trials have been conducted in any subgroup. Since licensure of palivizumab, new peer-reviewed publications provide greater insight into the epidemiology of disease caused by RSV.^{195–197} As a result of new data, the Bronchiolitis Guideline Committee and the Committee on Infectious Diseases have updated recommendations for use of prophylaxis.

PREMATURITY

Monthly palivizumab prophylaxis should be restricted to infants born before 29 weeks, 0 days' gestation, except for infants who qualify on the basis of congenital heart disease or chronic lung disease of prematurity. Data show that infants born at or after 29 weeks, 0 days' gestation have an RSV hospitalization rate similar to the rate of full-term infants.^{11,198} Infants with a gestational age of 28 weeks, 6 days or less who will be younger than 12 months at the start of the RSV season should receive a maximum of 5

monthly doses of palivizumab or until the end of the RSV season, whichever comes first. Depending on the month of birth, fewer than 5 monthly doses

will provide protection for most infants for the duration of the season.

CONGENITAL HEART DISEASE

Despite the large number of subjects enrolled, little benefit from palivizumab prophylaxis was found in the industry-sponsored cardiac study among infants in the cyanotic group (7.9% in control group versus 5.6% in palivizumab group, or 23 fewer hospitalizations per 1000 children; $P = .285$).¹⁹⁷ In the acyanotic group (11.8% vs 5.0%), there were 68 fewer RSV hospitalizations per 1000 prophylaxis recipients ($P = .003$).^{197,199,200}

CHRONIC LUNG DISEASE OF PREMATURITY

Palivizumab prophylaxis should be administered to infants and children younger than 12 months who develop chronic lung disease of prematurity, defined as a requirement for 28 days of more than 21% oxygen beginning at birth. If a child meets these criteria and is in the first 24 months of life and continues to require supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy within 6 months of the start of the RSV season, monthly prophylaxis should be administered for the remainder of the season.

NUMBER OF DOSES

Community outbreaks of RSV disease usually begin in November or December, peak in January or February, and end by late March or, at times, in April.⁴ Figure 1 shows the 2011–2012 bronchiolitis season, which is typical of most years. Because 5 monthly doses will provide more than 24 weeks of protective serum palivizumab concentration, administration of more than 5 monthly doses is not recommended within the continental United States. For infants who qualify for 5 monthly doses, initiation of prophylaxis in November and continua-

tion for a total of 5 doses will provide protection into April.²⁰¹ If prophylaxis is initiated in October, the fifth and final dose should be administered in February, and protection will last into March for most children.

SECOND YEAR OF LIFE

Because of the low risk of RSV hospitalization in the second year of life, palivizumab prophylaxis is not recommended for children in the second year of life with the following exception. Children who satisfy the definition of chronic lung disease of infancy and continue to require supplemental oxygen, chronic corticosteroid therapy, or diuretic therapy within 6 months of the onset of the second RSV season may be considered for a second season of prophylaxis.

OTHER CONDITIONS

Insufficient data are available to recommend routine use of prophylaxis in children with Down syndrome, cystic fibrosis, pulmonary abnormality, neuromuscular disease, or immune compromise.

Down Syndrome

Routine use of prophylaxis for children in the first year of life with Down syndrome is not recommended unless the child qualifies because of cardiac disease or prematurity.²⁰²

Cystic Fibrosis

Routine use of palivizumab prophylaxis in patients with cystic fibrosis is not recommended.^{203,204} Available studies indicate the incidence of RSV hospitalization in children with cystic fibrosis is low and unlikely to be different from children without cystic fibrosis. No evidence suggests a benefit from palivizumab prophylaxis in patients with cystic fibrosis. A randomized clinical trial involving 186 children with cystic

fibrosis from 40 centers reported 1 subject in each group was hospitalized because of RSV infection. Although this study was not powered for efficacy, no clinically meaningful differences in outcome were reported.²⁰⁵ A survey of cystic fibrosis center directors published in 2009 noted that palivizumab prophylaxis is not the standard of care for patients with cystic fibrosis.²⁰⁶ If a neonate is diagnosed with cystic fibrosis by newborn screening, RSV prophylaxis should not be administered if no other indications are present. A patient with cystic fibrosis with clinical evidence of chronic lung disease in the first year of life may be considered for prophylaxis.

Neuromuscular Disease and Pulmonary Abnormality

The risk of RSV hospitalization is not well defined in children with pulmonary abnormalities or neuromuscular disease that impairs ability to clear secretions from the lower airway because of ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy. No data on the relative risk of RSV hospitalization are available for this cohort. Selected infants with disease or congenital anomaly that impairs their ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life.

Immunocompromised Children

Population-based data are not available on the incidence or severity of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation, receive chemotherapy, or are immunocompromised because of other conditions. Prophylaxis may be considered for hematopoietic stem cell transplant

patients who undergo transplantation and are profoundly immunosuppressed during the RSV season.²⁰⁷

MISCELLANEOUS ISSUES

Prophylaxis is not recommended for prevention of nosocomial RSV disease in the NICU or hospital setting.^{208,209}

No evidence suggests palivizumab is a cost-effective measure to prevent recurrent wheezing in children. Prophylaxis should not be administered to reduce recurrent wheezing in later years.^{210,211}

Monthly prophylaxis in Alaska Native children who qualify should be determined by locally generated data regarding season onset and end.

Continuation of monthly prophylaxis for an infant or young child who experiences breakthrough RSV hospitalization is not recommended.

HAND HYGIENE

Key Action Statement 11a

All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 11a

Aggregate evidence quality	B
Benefits	Decreased transmission of disease
Risk, harm, cost	Possible hand irritation
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Key Action Statement 11b

All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 11b

Aggregate evidence quality	B
Benefits	Less hand irritation
Risk, harm, cost	If there is visible dirt on the hands, hand washing is necessary; alcohol-based rubs are not effective for <i>Clostridium difficile</i> , present a fire hazard, and have a slight increased cost
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Efforts should be made to decrease the spread of RSV and other causative agents of bronchiolitis in medical settings, especially in the hospital. Secretions from infected patients can be found on beds, crib railings, tabletops, and toys.¹² RSV, as well as many other viruses, can survive better on hard surfaces than on porous surfaces or hands. It can remain infectious on counter tops for ≥6 hours, on gowns or paper tissues for 20 to 30 minutes, and on skin for up to 20 minutes.²¹²

It has been shown that RSV can be carried and spread to others on the hands of

caregivers.²¹³ Studies have shown that health care workers have acquired infection by performing activities such as feeding, diaper change, and playing with the RSV-infected infant. Caregivers who had contact only with surfaces contaminated with the infants' secretions or touched inanimate objects in patients' rooms also acquired RSV. In these studies, health care workers contaminated their hands (or gloves) with RSV and inoculated their oral or conjunctival mucosa.²¹⁴ Frequent hand washing by health care workers has been shown to reduce the spread of RSV in the health care setting.²¹⁵

The Centers for Disease Control and Prevention published an extensive review of the hand-hygiene literature and made recommendations as to indications for hand washing and hand antisepsis.²¹⁶ Among the recommendations are that hands should be disinfected before and after direct contact with every patient, after contact with inanimate objects in the direct vicinity of the patient, and before putting on and after removing gloves. If hands are not visibly soiled, an alcohol-based rub is preferred. In guidelines published in 2009, the World Health Organization also recommended alcohol-based hand-rubs as the standard for hand hygiene in health care.²¹⁷ Specifically, systematic reviews show them to remove organisms more effectively, require less time, and irritate skin less often than hand washing with soap or other antiseptic agents and water. The availability of bedside alcohol-based solutions increased compliance with hand hygiene among health care workers.²¹⁴

When caring for hospitalized children with clinically diagnosed bronchiolitis, strict adherence to hand decontamination and use of personal protective equipment (ie, gloves and gowns) can reduce the risk of cross-infection in the health care setting.²¹⁵

Other methods of infection control in viral bronchiolitis include education of personnel and family members, surveillance for the onset of RSV season, and wearing masks when anticipating exposure to aerosolized secretions while performing patient care activities. Programs that implement the aforementioned principles, in conjunction with effective hand decontamination and cohorting of patients, have been shown to reduce the spread of RSV in the health care setting by 39% to 50%.^{218,219}

TOBACCO SMOKE

Key Action Statement 12a

Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 12a

Aggregate evidence quality	C
Benefits	Can identify infants and children at risk whose family may benefit from counseling, predicting risk of severe disease
Risk, harm, cost	Time to inquire
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parent may choose to deny tobacco use even though they are, in fact, users
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 12b

Clinicians should counsel caregivers about exposing the infant or

child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 12b

Aggregate evidence quality	B
Benefits	Reinforces the detrimental effects of smoking, potential to decrease smoking
Risk, harm, cost	Time to counsel
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to ignore counseling
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None
Notes	Counseling for tobacco smoke prevention should begin in the prenatal period and continue in family-centered care and at all well-infant visits

Tobacco smoke exposure increases the risk and severity of bronchiolitis. Strachan and Cook²²⁰ first delineated the effects of environmental tobacco smoke on rates of lower respiratory tract disease in infants in a meta-analysis including 40 studies. In a more recent systematic review, Jones et al²²¹ found a pooled odds ratio of 2.51 (95% CI 1.96 to 3.21) for tobacco smoke exposure and bronchiolitis hospitalization among the 7 studies specific to the condition. Other investigators have consistently reported tobacco smoke exposure increases both severity of illness and risk of hospitalization for bronchioli-

tis.^{222–225} The AAP issued a technical report on the risks of secondhand smoke in 2009. The report makes recommendations regarding effective ways to eliminate or reduce secondhand smoke exposure, including education of parents.²²⁶

Despite our knowledge of this important risk factor, there is evidence to suggest health care providers identify fewer than half of children exposed to tobacco smoke in the outpatient, inpatient, or ED settings.^{227–229} Furthermore, there is evidence that counseling parents in these settings is well received and has a measurable impact. Rosen et al²³⁰ performed a meta-analysis of the effects of interventions in pediatric settings on parental cessation and found a pooled risk ratio of 1.3 for cessation among the 18 studies reviewed.

In contrast to many of the other recommendations, protecting children from tobacco exposure is a recommendation that is primarily implemented outside of the clinical setting. As such, it is critical that parents are fully educated about the importance of not allowing smoking in the home and that smoke lingers on clothes and in the environment for prolonged periods.²³¹ It should be provided in plain language and in a respectful, culturally effective manner that is family centered, engages parents as partners in their child's health, and factors in their literacy, health literacy, and primary language needs.

BREASTFEEDING

Key Action Statement 13

Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections (Evidence Quality: Grade B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 13

Aggregate evidence quality	B
Benefits	May reduce the risk of bronchiolitis and other illnesses; multiple benefits of breastfeeding unrelated to bronchiolitis
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh risks
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to feed formula rather than breastfeed
Exclusions	None
Strength	Moderate recommendation
Notes	Education on breastfeeding should begin in the prenatal period

In 2012, the AAP presented a general policy on breastfeeding.²³² The policy statement was based on the proven benefits of breastfeeding for at least 6 months. Respiratory infections were shown to be significantly less common in breastfed children. A primary resource was a meta-analysis from the Agency for Healthcare Research and Quality that showed an overall 72% reduction in the risk of hospitalization secondary to respiratory diseases in infants who were exclusively breastfed for 4 or more months compared with those who were formula fed.²³³

The clinical evidence also supports decreased incidence and severity of illness in breastfed infants with bronchiolitis. Dornelles et al²³⁴ concluded that the duration of exclusive breastfeeding was inversely related to the length of oxygen use and the length of hospital stay in previously healthy infants with acute bronchiolitis. In a large prospective study in Australia, Oddy et al²³⁵ showed that breastfeeding for less than 6 months was associated

with an increased risk for 2 or more medical visits and hospital admission for wheezing lower respiratory illness. In Japan, Nishimura et al²³⁶ looked at 3 groups of RSV-positive infants defined as full, partial, or token breastfeeding. There were no significant differences in the hospitalization rate among the 3 groups; however, there were significant differences in the duration of hospitalization and the rate of requiring oxygen therapy, both favoring breastfeeding.

FAMILY EDUCATION

Key Action Statement 14

Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis (Evidence Quality: C; observational studies; Recommendation Strength; Moderate Recommendation).

Action Statement Profile KAS 14

Aggregate evidence quality	C
Benefits	Decreased transmission of disease, benefits of breastfeeding, promotion of judicious use of antibiotics, risks of infant lung damage attributable to tobacco smoke
Risk, harm, cost	Time to educate properly
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	Personnel is not specifically defined but should include all people who enter a patient's room
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Shared decision-making with parents about diagnosis and treatment of bronchiolitis is a key tenet of patient-centered care. Despite the absence of effective therapies for viral bronchiolitis, caregiver education by clinicians may have a significant impact on care patterns in the disease. Children with bronchiolitis typically suffer from symptoms for 2 to 3 weeks, and parents often seek care in multiple settings during that time period.²³⁷ Given that children with RSV generally shed virus for 1 to 2 weeks and from 30% to 70% of family members may become ill,^{238,239} education about prevention of transmission of disease is key. Restriction of visitors to newborns during the respiratory virus season should be considered. Consistent evidence suggests that parental education is helpful in the promotion of judicious use of antibiotics and that clinicians may misinterpret parental expectations about therapy unless the subject is openly discussed.^{240–242}

FUTURE RESEARCH NEEDS

- Better algorithms for predicting the course of illness
- Impact of clinical score on patient outcomes
- Evaluating different ethnic groups and varying response to treatments
- Does epinephrine alone reduce admission in outpatient settings?
- Additional studies on epinephrine in combination with dexamethasone or other corticosteroids
- Hypertonic saline studies in the outpatient setting and in in hospitals with shorter LOS
- More studies on nasogastric hydration
- More studies on tonicity of intravenous fluids

- Incidence of true AOM in bronchiolitis by using 2013 guideline definition
- More studies on deep suctioning and nasopharyngeal suctioning
- Strategies for monitoring oxygen saturation
- Use of home oxygen
- Appropriate cutoff for use of oxygen in high altitude
- Oxygen delivered by high-flow nasal cannula
- RSV vaccine and antiviral agents
- Use of palivizumab in special populations, such as cystic fibrosis, neuromuscular diseases, Down syndrome, immune deficiency
- Emphasis on parent satisfaction/patient-centered outcomes in all research (ie, not LOS as the only measure)

SUBCOMMITTEE ON BRONCHIOLITIS (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY, 2013–2014)

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APPENDIX 1 SEARCH TERMS BY TOPIC

Introduction

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

1. and exp Natural History/
2. and exp Epidemiology/
3. and (exp economics/ or exp “costs and cost analysis”/ or exp “cost allocation”/ or exp cost-benefit analysis/ or exp “cost control”/ or exp “cost of illness”/ or exp “cost sharing”/ or exp health care costs/ or exp health expenditures/)
4. and exp Risk Factors/

Limit to English Language AND Humans AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (“natural history” OR (MM “Epidemiology”) OR (MM “Costs and Cost Analysis”) OR (MM “Risk Factors”))

The Cochrane Library

Bronchiolitis AND (epidemiology OR risk factor OR cost)

Diagnosis/Severity

MedLine

exp BRONCHIOLITIS/di [Diagnosis] OR exp Bronchiolitis, Viral/di [Diagnosis]
limit to English Language AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MH “Bronchiolitis/DI”)

The Cochrane Library

Bronchiolitis AND Diagnosis

*Upper Respiratory Infection Symptoms

MedLine

(exp Bronchiolitis/ OR exp Bronchiolitis, Viral/) AND exp *Respiratory Tract Infections/

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”

CINAHL

(MM “Bronchiolitis+”) AND (MM “Respiratory Tract Infections+”)

The Cochrane Library

Bronchiolitis AND Respiratory Infection

Inhalation Therapies

*Bronchodilators & Corticosteroids

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

AND (exp Receptors, Adrenergic, β -2/ OR exp Receptors, Adrenergic, β / OR exp Receptors, Adrenergic, β -1/ OR β adrenergic*.mp. OR exp ALBUTEROL/ OR exp levalbuterol.mp. OR exp EPINEPHRINE/ OR exp Cholinergic Antagonists/ OR exp IPRATROPIUM/ OR exp Anti-Inflammatory Agents/ OR ics.mp. OR inhaled corticosteroid*.mp. OR exp Adrenal Cortex Hormones/ OR exp Leukotriene Antagonists/ OR montelukast.mp. OR exp Bronchodilator Agents/)

Limit to English Language AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (MM “Bronchodilator Agents”)

The Cochrane Library

Bronchiolitis AND (bronchodilator OR epinephrine OR albuterol OR salbutamol OR corticosteroid OR steroid)

*Hypertonic Saline

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

AND (exp Saline Solution, Hypertonic/ OR (aerosolized saline.mp. OR (exp AEROSOLS/ AND exp Sodium Chloride/)) OR (exp Sodium Chloride/ AND exp “Nebulizers and Vaporizers”/) OR nebulized saline.mp.)

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”

CINAHL

(MM “Bronchiolitis+”) AND (MM “Saline Solution, Hypertonic”)

The Cochrane Library

Bronchiolitis AND Hypertonic Saline

Oxygen

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

1. AND (exp Oxygen Inhalation Therapy/ OR supplemental oxygen.mp. OR oxygen saturation.mp. OR *Oxygen/ad, st [Administration & Dosage, Standards] OR oxygen treatment.mp.)
2. AND (exp OXIMETRY/ OR oximeters.mp.) AND (exp “Reproducibility of Results”/ OR reliability.mp. OR function.mp. OR technical specifications.mp.) OR (percutaneous measurement*.mp. OR exp Blood Gas Analysis/)

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”

CINAHL

(MM "Bronchiolitis+") AND

((MM "Oxygen Therapy") OR (MM "Oxygen+") OR (MM "Oxygen Saturation") OR (MM "Oximetry+") OR (MM "Pulse Oximetry") OR (MM "Blood Gas Monitoring, Transcutaneous"))

The Cochrane Library

Bronchiolitis AND (oxygen OR oximetry)

Chest Physiotherapy and Suctioning

MedLine

((("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

1. AND (Chest physiotherapy.mp. OR (exp Physical Therapy Techniques/ AND exp Thorax/))
2. AND (Nasal Suction.mp. OR (exp Suction/))

Limit to English Language

Limit to "all infant (birth to 23 months)" OR "newborn infant (birth to 1 month)" OR "infant (1 to 23 months)"

CINAHL

(MM "Bronchiolitis+")

1. AND ((MH "Chest Physiotherapy (Saba CCC)" OR (MH "Chest Physical Therapy+") OR (MH "Chest Physiotherapy (Iowa NIC)"))
2. AND (MH "Suctioning, Nasopharyngeal")

The Cochrane Library

Bronchiolitis AND (chest physiotherapy OR suction*)

Hydration

MedLine

((("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH])

NOT "bronchiolitis obliterans"[All Fields])

AND (exp Fluid Therapy/ AND (exp infusions, intravenous OR exp administration, oral))

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+") AND

((MM "Fluid Therapy+") OR (MM "Hydration Control (Saba CCC)" OR (MM "Hydration (Iowa NOC)"))

The Cochrane Library

Bronchiolitis AND (hydrat* OR fluid*)

SBI and Antibacterials

MedLine

((("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

AND

(exp Bacterial Infections/ OR exp Bacterial Pneumonia/ OR exp Otitis Media/ OR exp Meningitis/ OR exp *Anti-bacterial Agents/ OR exp Sepsis/ OR exp Urinary Tract Infections/ OR exp Bacteremia/ OR exp Tracheitis OR serious bacterial infection.mp.)

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+") AND

((MM "Pneumonia, Bacterial+") OR (MM "Bacterial Infections+") OR (MM "Otitis Media+") OR (MM "Meningitis, Bacterial+") OR (MM "Antimicrobial Agents+") OR (MM "Sepsis+") OR (MM

"Urinary Tract Infections+") OR (MM "Bacteremia"))

The Cochrane Library

Bronchiolitis AND (serious bacterial infection OR sepsis OR otitis media OR meningitis OR urinary tract infection OR bacteremia OR pneumonia OR antibacterial OR antimicrobial OR antibiotic)

Hand Hygiene, Tobacco, Breastfeeding, Parent Education

MedLine

((("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

1. AND (exp Hand Disinfection/ OR hand decontamination.mp. OR handwashing.mp.)
2. AND exp Tobacco/
3. AND (exp Breast Feeding/ OR exp Milk, Human/ OR exp Bottle Feeding/)

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+")

1. AND (MH "Handwashing+")
2. AND (MH "Tobacco+")
3. AND (MH "Breast Feeding+" OR MH "Milk, Human+" OR MH "Bottle Feeding+")

The Cochrane Library

Bronchiolitis

1. AND (Breast Feeding OR breastfeeding)
2. AND tobacco
3. AND (hand hygiene OR handwashing OR hand decontamination)

Bronchiolitis Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
 - The Diagnosis, Management, and Prevention of Bronchiolitis
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Bronchiolitis
- AAP Patient Education Handout
 - *Bronchiolitis and Your Young Child*

Action Statement Summary

The Diagnosis, Management, and Prevention of Bronchiolitis

Key Action Statement 1a

Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 1b

Clinicians should assess risk factors for severe disease, such as age <12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about evaluation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 1c

When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 2

Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 3

Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 4a

Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 4b

Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak Recommendation [based on randomized controlled trials with inconsistent findings]).

Key Action Statement 5

Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).

Key Action Statement 6a

Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).

Key Action Statement 6b

Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: C; Recommendation Strength: Weak Recommendation [based on lower-level evidence]).

Key Action Statement 7

Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 8

Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one. (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 9

Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).

Key Action Statement 10a

Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 10b

Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks, 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 10c

Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the RSV season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 11a

All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 11b

All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 12a

Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).

Key Action Statement 12b

Clinicians should counsel caregivers about exposing the infant or child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 13

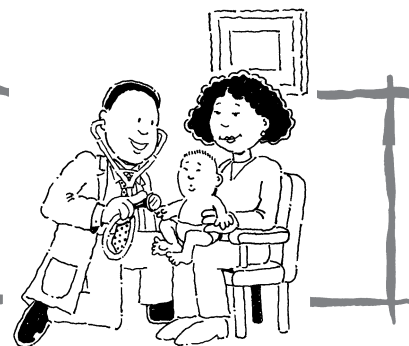
Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections (Evidence Quality: Grade B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 14

Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis (Evidence Quality: C; observational studies; Recommendation Strength: Moderate Recommendation).

Coding Quick Reference for Bronchiolitis	
<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
466.11 Acute bronchiolitis due to respiratory syncytial virus (RSV)	J21.0 Acute bronchiolitis due to syncytial virus
466.19 Acute bronchiolitis due to other infectious organisms	J21.8 Acute bronchiolitis due to other specified organisms

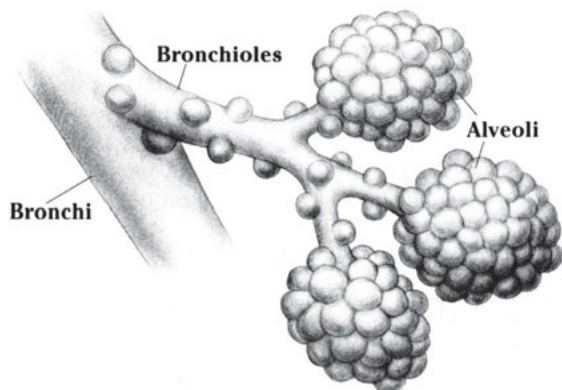
Bronchiolitis and Your Young Child



Bronchiolitis is a common respiratory illness among infants. One of its symptoms is trouble breathing, which can be scary for parents and young children. Read on for more information from the American Academy of Pediatrics about bronchiolitis, causes, signs and symptoms, how to treat it, and how to prevent it.

What is bronchiolitis?

Bronchiolitis is an infection that causes the small breathing tubes of the lungs (bronchioles) to swell. This blocks airflow through the lungs, making it hard to breathe. It occurs most often in infants because their airways are smaller and more easily blocked than in older children. Bronchiolitis is not the same as bronchitis, which is an infection of the larger, more central airways that typically causes problems in adults.



What causes bronchiolitis?

Bronchiolitis is caused by one of several respiratory viruses such as influenza, respiratory syncytial virus (RSV), parainfluenza, and human metapneumovirus. Other viruses can also cause bronchiolitis.

Infants with RSV infection are more likely to get bronchiolitis with wheezing and difficulty breathing. Most adults and many older children with RSV infection only get a cold. RSV is spread by contact with an infected person's mucus or saliva (respiratory droplets produced during coughing or wheezing). It often spreads through families and child care centers. (See "How can you prevent your baby from getting bronchiolitis?").

What are the signs and symptoms of bronchiolitis?

Bronchiolitis often starts with signs of a cold, such as a runny nose, mild cough, and fever. After 1 or 2 days, the cough may get worse and an infant will begin to breathe faster. Your child may become dehydrated if he cannot comfortably drink fluids.

If your child shows any signs of troubled breathing or dehydration, call your child's doctor.

Signs of troubled breathing

- He may widen his nostrils and squeeze the muscles under his rib cage to try to get more air into and out of his lungs.
- When he breathes, he may grunt and tighten his stomach muscles.
- He will make a high-pitched whistling sound, called a wheeze, when he breathes out.
- He may have trouble drinking because he may have trouble sucking and swallowing.
- If it gets very hard for him to breathe, you may notice a bluish tint around his lips and fingertips. This tells you his airways are so blocked that there is not enough oxygen getting into his blood.

Signs of dehydration

- Drinking less than normal
- Dry mouth
- Crying without tears
- Urinating less often than normal

Bronchiolitis and children with severe chronic illness

Bronchiolitis may cause more severe illness in children who have a chronic illness. If you think your child has bronchiolitis and she has any of the following conditions, call her doctor:

- Cystic fibrosis
- Congenital heart disease
- Chronic lung disease (seen in some infants who were on breathing machines or respirators as newborns)
- Immune deficiency disease (eg, acquired immunodeficiency syndrome [AIDS])
- Organ or bone marrow transplant
- A cancer for which she is receiving chemotherapy

Can bronchiolitis be treated at home?

There is no specific treatment for RSV or other viruses that cause bronchiolitis. Antibiotics are not helpful because they treat illnesses caused by bacteria, not viruses. However, you can try to ease your child's symptoms.

To relieve a stuffy nose

- Thin the mucus using saline nose drops recommended by your child's doctor. Never use nonprescription nose drops that contain medicine.
- Clear your baby's nose with a suction bulb.

Squeeze the bulb first. Gently put the rubber tip into one nostril, and slowly release the bulb.

This suction will draw the clogged mucus out of the nose. This works best when your baby is younger than 6 months.

To relieve fever

Give your baby acetaminophen. (Follow the recommended dosage for your baby's age.) Do not give your baby aspirin because it has been associated with Reye syndrome, a disease that affects the liver and brain. Check with your child's doctor first before giving any other cold medicines.

To prevent dehydration

Make sure your baby drinks lots of fluid. She may want clear liquids rather than milk or formula. She may feed more slowly or not feel like eating because she is having trouble breathing.

How will your child's doctor treat bronchiolitis?

Your child's doctor will evaluate your child and advise you on nasal suctioning, fever control, and observation, as well as when to call back.

Some children with bronchiolitis need to be treated in a hospital for breathing problems or dehydration. Breathing problems may need to be treated with oxygen and medicine. Dehydration is treated with a special liquid diet or intravenous (IV) fluids.

In very rare cases when these treatments aren't working, an infant might have to be put on a respirator. This is usually only temporary until the infection is gone.

How can you prevent your baby from getting bronchiolitis?

The best steps you can follow to reduce the risk that your baby becomes infected with RSV or other viruses that cause bronchiolitis include

- Make sure everyone washes their hands before touching your baby.
- Keep your baby away from anyone who has a cold, fever, or runny nose.
- Avoid sharing eating utensils and drinking cups with anyone who has a cold, fever, or runny nose.

If you have questions about the treatment of bronchiolitis, call your child's doctor.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

American Academy
of Pediatrics



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The American Academy of Pediatrics (AAP) is an organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults.

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Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

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- *Clinical Practice Guideline*
- *Technical Report*
 - *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



Readers of this clinical practice guideline are urged to review the technical report to enhance the evidence-based decision-making process. The full technical report is available following the clinical practice guideline and on the companion CD-ROM.

CLINICAL PRACTICE GUIDELINE

Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

abstract

FREE

Over the past 3 decades, the prevalence of childhood obesity has increased dramatically in North America, ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. The rapid emergence of childhood T2DM poses challenges to many physicians who find themselves generally ill-equipped to treat adult diseases encountered in children. This clinical practice guideline was developed to provide evidence-based recommendations on managing 10- to 18-year-old patients in whom T2DM has been diagnosed. The American Academy of Pediatrics (AAP) convened a Subcommittee on Management of T2DM in Children and Adolescents with the support of the American Diabetes Association, the Pediatric Endocrine Society, the American Academy of Family Physicians, and the Academy of Nutrition and Dietetics (formerly the American Dietetic Association). These groups collaborated to develop an evidence report that served as a major source of information for these practice guideline recommendations. The guideline emphasizes the use of management modalities that have been shown to affect clinical outcomes in this pediatric population. Recommendations are made for situations in which either insulin or metformin is the preferred first-line treatment of children and adolescents with T2DM. The recommendations suggest integrating lifestyle modifications (ie, diet and exercise) in concert with medication rather than as an isolated initial treatment approach. Guidelines for frequency of monitoring hemoglobin A1c (HbA1c) and finger-stick blood glucose (BG) concentrations are presented. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendation. The clinical practice guideline underwent peer review before it was approved by the AAP. This clinical practice guideline is not intended to replace clinical judgment or establish a protocol for the care of all children with T2DM, and its recommendations may not provide the only appropriate approach to the management of children with T2DM. Providers should consult experts trained in the care of children and adolescents with T2DM when treatment goals are not met or when therapy with insulin is initiated. The AAP acknowledges that some primary care clinicians may not be confident of their ability to successfully treat T2DM in a child because of the child's age, coexisting conditions, and/or other concerns. At any point at which a clinician feels he or she is not adequately trained or is uncertain about treatment, a referral to a pediatric medical subspecialist should be made. If a diagnosis of T2DM is made by a pediatric medical subspecialist, the primary care clinician should develop a comanagement strategy with the subspecialist to ensure that the child continues to receive appropriate care consistent with a medical home model in which the pediatrician partners with parents to ensure that all health needs are met. *Pediatrics* 2013;131:364–382

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KEY WORDS

diabetes, type 2 diabetes mellitus, childhood, youth, clinical practice guidelines, comanagement, management, treatment

ABBREVIATIONS

AAP—American Academy of Pediatrics
 AAFP—American Academy of Family Physicians
 BG—blood glucose
 FDA—US Food and Drug Administration
 HbA1c—hemoglobin A1c
 PES—Pediatric Endocrine Society
 T1DM—type 1 diabetes mellitus
 T2DM—type 2 diabetes mellitus
 TODAY—Treatment Options for type 2 Diabetes in Adolescents and Youth

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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Key action statements are as follows:

1. Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between types 1 and 2 diabetes mellitus is unclear and, in usual cases, should initiate insulin therapy for patients
 - a. who have random venous or plasma BG concentrations ≥ 250 mg/dL; or
 - b. whose HbA1c is $>9\%$.
2. In all other instances, clinicians should initiate a lifestyle modification program, including nutrition and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM.
3. The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for finger-stick BG and HbA1c concentrations are not being met (intensification is defined in the Definitions box).
4. The committee suggests that clinicians advise patients to monitor finger-stick BG (see Key Action Statement 4 in the guideline for further details) concentrations in patients who
 - a. are taking insulin or other medications with a risk of hypoglycemia; or
 - b. are initiating or changing their diabetes treatment regimen; or
 - c. have not met treatment goals; or
 - d. have intercurrent illnesses.
5. The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in their dietary or nutrition counseling of patients with T2DM at the time of diagnosis and as part of ongoing management.
6. The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic "screen time" to less than 2 hours a day.

Definitions

Adolescent: an individual in various stages of maturity, generally considered to be between 12 and 18 years of age.

Childhood T2DM: disease in the child who typically

- is overweight or obese (BMI ≥ 85 th–94th and >95 th percentile for age and gender, respectively);
- has a strong family history of T2DM;
- has substantial residual insulin secretory capacity at diagnosis (reflected by normal or elevated insulin and C-peptide concentrations);
- has insidious onset of disease;
- demonstrates insulin resistance (including clinical evidence of polycystic ovarian syndrome or acanthosis nigricans);
- lacks evidence for diabetic autoimmunity (negative for autoantibodies typically associated with T1DM). These patients are more likely to have hypertension and dyslipidemia than are those with T1DM.

Clinician: any provider within his or her scope of practice; includes medical practitioners (including physicians and physician extenders), dietitians, psychologists, and nurses.

Diabetes: according to the American Diabetes Association criteria, defined as

1. HbA1c $\geq 6.5\%$ (test performed in an appropriately certified laboratory); or
2. fasting (defined as no caloric intake for at least 8 hours) plasma glucose ≥ 126 mg/dL (7.0 mmol/L); or
3. 2-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test performed as described by the World Health Organization by using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water; or
4. a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) with symptoms of hyperglycemia.

(In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.)

Diabetic ketoacidosis: acidosis resulting from an absolute or relative insulin deficiency, causing fat breakdown and formation of β hydroxybutyrate. Symptoms include nausea, vomiting, dehydration, Kussmaul respirations, and altered mental status.

Fasting blood glucose: blood glucose obtained before the first meal of the day and after a fast of at least 8 hours.

Glucose toxicity: The effect of high blood glucose causing both insulin resistance and impaired β -cell production of insulin.

Intensification: Increase frequency of blood glucose monitoring and adjustment of the dose and type of medication in an attempt to normalize blood glucose concentrations.

Intercurrent illnesses: Febrile illnesses or associated symptoms severe enough to cause the patient to stay home from school and/or seek medical care.

Microalbuminuria: Albumin:creatinine ratio ≥ 30 mg/g creatinine but < 300 mg/g creatinine.

Moderate hyperglycemia: blood glucose = 180–250 mg/dL.

Moderate-to-vigorous exercise: exercise that makes the individual breathe hard and perspire and that raises his or her heart rate. An easy way to define exercise intensity for patients is the “talk test”: during moderate physical activity a person can talk, but not sing. During vigorous activity, a person cannot talk without pausing to catch a breath.

Obese: BMI ≥ 95 th percentile for age and gender.

Overweight: BMI between the 85th and 94th percentile for age and gender.

Prediabetes: Fasting plasma glucose ≥ 100 –125 mg/dL or 2-hour glucose concentration during an oral glucose tolerance test ≥ 126 but < 200 mg/dL or an HbA1c of 5.7% to 6.4%.

Severe hyperglycemia: blood glucose > 250 mg/dL.

Thiazolidinediones (TZDs): Oral hypoglycemic agents that exert their effect at least in part by activation of the peroxisome proliferator-activated receptor γ .

Type 1 diabetes mellitus (T1DM): Diabetes secondary to autoimmune destruction of β cells resulting in absolute (complete or near complete) insulin deficiency and requiring insulin injections for management.

Type 2 diabetes mellitus (T2DM): The investigators’ designation of the diagnosis was used for the purposes of the literature review. The committee acknowledges the distinction between T1DM and T2DM in this population is not always clear cut, and clinical judgment plays an important role. Typically, this diagnosis is made when hyperglycemia is secondary to insulin resistance accompanied by impaired β -cell function resulting in inadequate insulin production to compensate for the degree of insulin resistance.

Youth: used interchangeably with “adolescent” in this document.

INTRODUCTION

Over the past 3 decades, the prevalence of childhood obesity has increased dramatically in North America,^{1–5} ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. Currently, in the United States, up to 1 in 3 new cases of diabetes mellitus diagnosed in youth younger than 18 years is T2DM

(depending on the ethnic composition of the patient population),^{6,7} with a disproportionate representation in ethnic minorities^{8,9} and occurring most commonly among youth between 10 and 19 years of age.^{5,10} This trend is not limited to the United States but is occurring internationally¹¹; it is projected that by the year 2030, an estimated 366 million people worldwide will have diabetes mellitus.¹²

The rapid emergence of childhood T2DM poses challenges to many physicians who find themselves generally ill-equipped to treat adult diseases encountered in children. Most diabetes education materials designed for pediatric patients are directed primarily to families of children with type 1 diabetes mellitus (T1DM) and emphasize insulin treatment and glucose monitoring, which may or may not be appropriate for children with

T2DM.^{13,14} The National Diabetes Education Program TIP sheets (which can be ordered or downloaded from www.yourdiabetesinfo.org or ndep.nih.gov) provide guidance on healthy eating, physical activity, and dealing with T2DM in children and adolescents, but few other resources are available that are directly targeted at youth with this disease.¹⁵ Most medications used for T2DM have been tested for safety and efficacy only in people older than 18 years, and there is scant scientific evidence for optimal management of children with T2DM.^{16,17} Recognizing the scarcity of evidence-based data, this report provides a set of guidelines for the management and treatment of children with T2DM that is based on a review of current medical literature covering a period from January 1, 1990, to July 1, 2008.

Despite these limitations, the practicing physician is likely to be faced with the need to provide care for children with T2DM. Thus, the American Academy of Pediatrics (AAP), the Pediatric Endocrine Society (PES), the American Academy of Family Physicians (AAFP), American Diabetes Association, and the Academy of Nutrition and Dietetics (formerly the American Dietetic Association) partnered to develop a set of guidelines that might benefit endocrinologists and generalists, including pediatricians and family physicians alike. This clinical practice guideline may not provide the only appropriate approach to the management of children with T2DM. It is not expected to serve as a sole source of guidance in the management of children and adolescents with T2DM, nor is it intended to replace clinical judgment or establish a protocol for the care of all children with this condition. Rather, it is intended to assist clinicians in decision-making. Primary care providers should endeavor to obtain the requisite skills to care for children and adolescents with

T2DM, and should communicate and work closely with a diabetes team of subspecialists when such consultation is available, practical, and appropriate. The frequency of such consultations will vary, but should usually be obtained at diagnosis and then at least annually if possible. When treatment goals are not met, the committee encourages clinicians to consult with an expert trained in the care of children and adolescents with T2DM.^{18,19} When first-line therapy (eg, metformin) fails, recommendations for intensifying therapy should be generally the same for pediatric and adult populations. The picture is constantly changing, however, as new drugs are introduced, and some drugs that initially appeared to be safe demonstrate adverse effects with wider use. Clinicians should, therefore, remain alert to new developments with regard to treatment of T2DM. Seeking the advice of an expert can help ensure that the treatment goals are appropriately set and that clinicians benefit from cutting-edge treatment information in this rapidly changing area.

The Importance of Family-Centered Diabetes Care

Family structure, support, and education help inform clinical decision-making and negotiations with the patient and family about medical preferences that affect medical decisions, independent of existing clinical recommendations. Because adherence is a major issue in any lifestyle intervention, engaging the family is critical not only to maintain needed changes in lifestyle but also to foster medication adherence.^{20–22} The family's ideal role in lifestyle interventions varies, however, depending on the child's age. Behavioral interventions in younger children have shown a favorable effect. With adolescents, however, interventions based on target-age behaviors (eg, including phone or Internet-based

interventions as well as face-to-face or peer-enhanced activities) appear to foster better results, at least for weight management.²³

Success in making lifestyle changes to attain therapeutic goals requires the initial and ongoing education of the patient and the entire family about healthy nutrition and exercise. Any behavior change recommendations must establish realistic goals and take into account the families' health beliefs and behaviors. Understanding the patient and family's perception of the disease (and overweight status) before establishing a management plan is important to dispel misconceptions and promote adherence.²⁴ Because T2DM disproportionately affects minority populations, there is a need to ensure culturally appropriate, family-centered care along with ongoing education.^{25–28} Several observational studies cite the importance of addressing cultural issues within the family.^{20–22}

Restrictions in Creating This Document

In developing these guidelines, the following restrictions governed the committee's work:

- Although the importance of diabetes detection and screening of at-risk populations is acknowledged and referenced, the guidelines are restricted to patients meeting the diagnostic criteria for diabetes (eg, this document focuses on treatment postdiagnosis). Specifically, this document and its recommendations do not pertain to patients with impaired fasting plasma glucose (100–125 mg/dL) or impaired glucose tolerance (2-hour oral glucose tolerance test plasma glucose: 140–200 mg/dL) or isolated insulin resistance.
- Although it is noted that the distinction between types 1 and 2 diabetes mellitus in children may be

difficult,^{29,30} these recommendations pertain specifically to patients 10 to less than 18 years of age with T2DM (as defined above).

- Although the importance of high-risk care and glycemic control in pregnancy, including pregravid glycemia, is affirmed, the evidence considered and recommendations contained in this document do not pertain to diabetes in pregnancy, including diabetes in pregnant adolescents.
- Recommended screening schedules and management tools for select comorbid conditions (hypertension, dyslipidemia, nephropathy, microalbuminuria, and depression) are provided as resources in the accompanying technical report.³¹ These therapeutic recommendations were adapted from other recommended guideline documents with references, without an independent assessment of their supporting evidence.

METHODS

A systematic review was performed and is described in detail in the accompanying technical report.³¹ To develop the clinical practice guideline on the management of T2DM in children and adolescents, the AAP convened the Subcommittee on Management of T2DM in Children and Adolescents with the support of the American Diabetes Association, the PES, the AAFP, and the Academy of Nutrition and Dietetics. The subcommittee was co-chaired by 2 pediatric endocrinologists preeminent in their field and included experts in general pediatrics, family medicine, nutrition, Native American health, epidemiology, and medical informatics/guideline methodology. All panel members reviewed the AAP policy on Conflict of Interest and Voluntary Disclosure and declared all potential conflicts (see conflicts statements in the Task Force member list).

These groups partnered to develop an evidence report that served as a major source of information for these practice guideline recommendations.³¹ Specific clinical questions addressed in the evidence review were as follows: (1) the effectiveness of treatment modalities for T2DM in children and adolescents, (2) the efficacy of pharmaceutical therapies for treatment of children and adolescents with T2DM, (3) appropriate recommendations for screening for comorbidities typically associated with T2DM in children and adolescents, and (4) treatment recommendations for comorbidities of T2DM in children and adolescents. The accompanying technical report contains more information on comorbidities.³¹

Epidemiologic project staff searched Medline, the Cochrane Collaboration, and Embase. MESH terms used in various combinations in the search included diabetes, mellitus, type 2, type 1, treatment, prevention, diet, pediatric, T2DM, T1DM, NIDDM, metformin, lifestyle, RCT, meta-analysis, child, adolescent, therapeutics, control, adult, obese, gestational, polycystic ovary syndrome, metabolic syndrome, cardiovascular, dyslipidemia, men, and women. In addition, the Boolean

operators NOT, AND, OR were included in various combinations. Articles addressing treatment of diabetes mellitus were prospectively limited to those that were published in English between January 1990 and June 2008, included abstracts, and addressed children between the ages of 120 and 215 months with an established diagnosis of T2DM. Studies in adults were considered for inclusion if >10% of the study population was 45 years of age or younger. The Medline search limits included the following: clinical trial; meta-analysis; randomized controlled trial; review; child: 6–12 years; and adolescent: 13–18 years. Additional articles were identified by review of reference lists of relevant articles and ongoing studies recommended by a technical expert advisory group. All articles were reviewed for compliance with the search limitations and appropriateness for inclusion in this document.

Initially, 199 abstracts were identified for possible inclusion, of which 52 were retained for systematic review. Results of the literature review were presented in evidence tables and published in the final evidence report. An additional literature search of Medline and the Cochrane Database of

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs* or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)	Option	
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation Recommendation	

FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation.³² RCT, randomized controlled trial; Rec, recommendation.

TABLE 1 Definitions and Recommendation Implications

Statement	Definition	Implication
Strong recommendation	A <i>strong recommendation</i> in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A <i>recommendation</i> in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	<i>Options</i> define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	<i>No recommendation</i> indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

It should be noted that, because childhood T2DM is a relatively recent medical phenomenon, there is a paucity of evidence for many or most of the recommendations provided. In some cases, supporting references for a specific recommendation are provided that do not deal specifically with childhood T2DM, such as T1DM, childhood obesity, or childhood "prediabetes," or that were not included in the original comprehensive search. Committee members have made every effort to identify those references that did not affect or alter the level of evidence for specific recommendations.

Systematic Reviews was performed in July 2009 for articles discussing recommendations for screening and treatment of 5 recognized comorbidities of T2DM: cardiovascular disease, dyslipidemia, retinopathy, nephropathy, and peripheral vascular disease. Search criteria were the same as for the search on treatment of T2DM, with the inclusion of the term "type 1 diabetes mellitus." Search terms included, in various combinations, the following: diabetes, mellitus, type 2, type 1, pediatric, T2DM, T1DM, NIDDM, hyperlipidemia, retinopathy, microalbuminuria, comorbidities, screening, RCT, meta-analysis, child, and adolescent. Boolean operators and search limits mirrored those of the primary search.

An additional 336 abstracts were identified for possible inclusion, of which 26 were retained for systematic review. Results of this subsequent literature review were also presented in evidence tables and published in

the final evidence report. An epidemiologist appraised the methodologic quality of the research before it was considered by the committee members.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines,"³² was followed in designating levels of recommendation (see Fig 1 and Table 1).

To ensure that these recommendations can be effectively implemented, the Guidelines Review Group at Yale Center for Medical Informatics provided feedback

on a late draft of these recommendations, using the Guideline Implementability Appraisal.³³ Several potential obstacles to successful implementation were identified and resolved in the final guideline. Evidence was incorporated systematically into 6 key action statements about appropriate management facilitated by BRIDGE-Wiz software (Building Recommendations in a Developer's Guideline Editor; Yale Center for Medical Informatics).

A draft version of this clinical practice guideline underwent extensive peer review by 8 groups within the AAP, the American Diabetes Association, PES, AAFP, and the Academy of Nutrition and Dietetics. Members of the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and incorporated into the guideline, as appropriate. All AAP guidelines are reviewed every 5 years.

KEY ACTION STATEMENTS

Key Action Statement 1

Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between T1DM and T2DM is unclear; and, in usual cases, should initiate insulin therapy for patients:

- a. who have random venous or plasma BG concentrations ≥ 250 mg/dL; or**
- b. whose HbA1c is $>9\%$.**

(Strong Recommendation: evidence quality X, validating studies cannot be performed, and C, observational studies and expert opinion; preponderance of benefit over harm.)

process, blood glucose (BG) concentrations may be normal much of the time and the patient likely will be asymptomatic. At this stage, the disease may only be detected by abnormal BG concentrations identified during screening. As insulin secretion declines further, the patient is likely to develop symptoms of hyperglycemia, occasionally with ketosis or frank ketoacidosis. High glucose concentrations can cause a reversible toxicity to islet β cells that contributes further to insulin deficiency. Of adolescents in whom T2DM is subsequently diagnosed, 5% to 25% present with ketoacidosis.³⁴ Diabetic ketoacidosis must be treated with insulin and fluid and electrolyte replacement to prevent worsening

T2DM. Patients in whom ketoacidosis is diagnosed require immediate treatment with insulin and fluid replacement in an inpatient setting under the supervision of a physician who is experienced in treating this complication. Youth and adolescents who present with T2DM with poor glycemic control (BG concentrations ≥ 250 mg/dL or HbA1c $>9\%$) but who lack evidence of ketosis or ketoacidosis may also benefit from initial treatment with insulin, at least on a short-term basis.³⁴ This allows for quicker restoration of glycemic control and, theoretically, may allow islet β cells to “rest and recover.”^{35,36} Furthermore, it has been noted that initiation of insulin may increase long-term adherence to treatment in children and adolescents with T2DM by enhancing the patient’s perception of the seriousness of the disease.^{7,37–40} Many patients with T2DM can be weaned gradually from insulin therapy and subsequently managed with metformin and lifestyle modification.³⁴ As noted previously, in some children and adolescents with newly diagnosed diabetes mellitus, it may be difficult to distinguish between type 1 and type 2 disease (eg, an obese child presenting with ketosis).^{39,41} These patients are best managed initially with insulin therapy while appropriate tests are performed to differentiate between T1DM and T2DM. The care of children and adolescents who have either newly diagnosed T2DM or undifferentiated-type diabetes and who require initial insulin treatment should be supervised by a physician experienced in treating diabetic patients with insulin.

Action Statement Profile KAS 1

Aggregate evidence quality	X (validating studies cannot be performed)
Benefits	Avoidance of progression of diabetic ketoacidosis (DKA) and worsening metabolic acidosis; resolution of acidosis and hyperglycemia; avoidance of coma and/or death. Quicker restoration of glycemic control, potentially allowing islet β cells to “rest and recover,” increasing long-term adherence to treatment; avoiding progression to DKA if T1DM. Avoiding hospitalization. Avoidance of potential risks associated with the use of other agents (eg, abdominal discomfort, bloating, loose stools with metformin; possible cardiovascular risks with sulfonylureas).
Harms/risks/cost	Potential for hypoglycemia, insulin-induced weight gain, cost, patient discomfort from injection, necessity for BG testing, more time required by the health care team for patient training.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Extensive clinical experience of the expert panel was relied on in making this recommendation.
Role of patient preferences	Minimal.
Exclusions	None.
Intentional vagueness	None.
Strength	Strong recommendation.

The presentation of T2DM in children and adolescents varies according to the disease stage. Early in the disease, before diabetes diagnostic criteria are met, insulin resistance predominates with compensatory high insulin secretion, resulting in normoglycemia. Over time, β cells lose their ability to secrete adequate amounts of insulin to overcome insulin resistance, and hyperglycemia results. Early in this

metabolic acidosis, coma, and death. Children and adolescents with symptoms of hyperglycemia (polyuria, polydipsia, and polyphagia) who are diagnosed with diabetes mellitus should be evaluated for ketosis (serum or urine ketones) and, if positive, for ketoacidosis (venous pH), even if their phenotype and risk factor status (obesity, acanthosis nigricans, positive family history of T2DM) suggests

Key Action Statement 2

In all other instances, clinicians should initiate a lifestyle modification program, including nutrition

and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM. (Strong recommendation: evidence quality B; 1 RCT showing improved outcomes with metformin versus lifestyle; preponderance of benefits over harms.)

Action Statement Profile KAS 2

Aggregate evidence quality	B (1 randomized controlled trial showing improved outcomes with metformin versus lifestyle combined with expert opinion).
Benefit	Lower HbA1c, target HbA1c sustained longer, less early deterioration of BG, less chance of weight gain, improved insulin sensitivity, improved lipid profile.
Harm (of using metformin)	Gastrointestinal adverse effects or potential for lactic acidosis and vitamin B ₁₂ deficiency, cost of medications, cost to administer, need for additional instruction about medication, self-monitoring blood glucose (SMBG), perceived difficulty of insulin use, possible metabolic deterioration if T1DM is misdiagnosed and treated as T2DM, potential risk of lactic acidosis in the setting of ketosis or significant dehydration. It should be noted that there have been no cases reported of vitamin B ₁₂ deficiency or lactic acidosis with the use of metformin in children.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Committee members valued faster achievement of BG control over not medicating children.
Role of patient preferences	Moderate; precise implementation recommendations likely will be dictated by patient preferences regarding healthy nutrition, potential medication adverse reaction, exercise, and physical activity.
Exclusions	Although the recommendation to start metformin applies to all, certain children and adolescents with T2DM will not be able to tolerate metformin. In addition, certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely. Nevertheless, this recommendation applies to the vast majority of children and adolescents with T2DM.
Intentional vagueness	None.
Policy level	Strong recommendation.

Metformin as First-Line Therapy

Because of the low success rate with diet and exercise alone in pediatric patients diagnosed with T2DM, metformin should be initiated along with the promotion of lifestyle changes, unless insulin is needed to reverse glucose toxicity in the case of significant hyperglycemia or ketoacidosis (see Key Action Statement 1). Because gastrointestinal adverse effects are common with metformin therapy, the

committee recommends starting the drug at a low dose of 500 mg daily, increasing by 500 mg every 1 to 2 weeks, up to an ideal and maximum dose of 2000 mg daily in divided doses.⁴¹ It should be noted that the main gastrointestinal adverse effects (abdominal pain, bloating, loose stools) present at initiation of metformin often are transient and often

credible RCTs in adolescents with T2DM. The evidence to recommend initiating metformin at diagnosis along with lifestyle changes comes from 1 RCT, several observational studies, and consensus recommendations.

Lifestyle modifications (including nutrition interventions and increased physical activity) have long been the cornerstone of therapy for T2DM. Yet, medical practitioners recognize that effecting these changes is both challenging and often accompanied by regression over time to behaviors not conducive to maintaining the target range of BG concentrations. In pediatric patients, lifestyle change is most likely to be successful when a multidisciplinary approach is used and the entire family is involved. (Encouragement of healthy eating and physical exercise are discussed in Key Action Statements 5 and 6.) Unfortunately, efforts at lifestyle change often fail for a variety of reasons, including high rates of loss to follow-up; a high rate of depression in teenagers, which affects adherence; and peer pressure to participate in activities that often center on unhealthy eating.

Expert consensus is that fewer than 10% of pediatric T2DM patients will attain their BG goals through lifestyle interventions alone.^{6,35,44} It is possible that the poor long-term success rates observed from lifestyle interventions stem from patients' perception that the intervention is not important because medications are not being prescribed. One might speculate that prescribing medications, particularly insulin therapy, may convey a greater degree of concern for the patient's health and the seriousness of the diagnosis, relative to that conveyed when medications are not needed, and that improved treatment adherence and follow-up may result from the use of medication. Indeed, 2 prospective observational studies revealed that treatment with

disappear completely if medication is continued. Generally, doses higher than 2000 mg daily do not provide additional therapeutic benefit.^{34,42,43} In addition, the use of extended-release metformin, especially with evening dosing, may be considered, although data regarding the frequency of adverse effects with this preparation are scarce. Metformin is generally better tolerated when taken with food. It is important to recognize the paucity of

lifestyle modification alone is associated with a higher rate of loss to follow-up than that found in patients who receive medication.⁴⁵

Before initiating treatment with metformin, a number of important considerations must be taken into account. First, it is important to determine whether the child with a new diagnosis has T1DM or T2DM, and it is critical to err on the side of caution if there is any uncertainty. The 2009 *Clinical Practice Consensus Guidelines on Type 2 Diabetes in Children and Adolescents* from the International Society for Pediatric and Adolescent Diabetes provides more information on the classification of diabetes in children and adolescents with new diagnoses.⁴⁶ If the diagnosis is unclear (as may be the case when an obese child with diabetes presents also with ketosis), the adolescent must be treated with insulin until the T2DM diagnosis is confirmed.⁴⁷ Although it is recognized that some children with newly diagnosed T2DM may respond to metformin alone, the committee believes that the presence of either ketosis or ketoacidosis dictates an absolute initial requirement for insulin replacement. (This is addressed in Key Action Statement 1.) Although there is little debate that a child presenting with significant hyperglycemia and/or ketosis requires insulin, children presenting with more modest levels of hyperglycemia (eg, random BG of 200–249 mg/dL) or asymptomatic T2DM present additional therapeutic challenges to the clinician. In such cases, metformin alone, insulin alone, or metformin with insulin all represent reasonable options. Additional agents are likely to become reasonable options for initial pharmacologic management in the near future. Although metformin and insulin are the only antidiabetic agents currently approved by the US Food and

Drug Administration (FDA) for use in children, both thiazolidinediones and incretins are occasionally used in adolescents younger than 18 years.⁴⁸

Metformin is recommended as the initial pharmacologic agent in adolescents presenting with mild hyperglycemia and without ketonuria or severe hyperglycemia. In addition to improving hepatic insulin sensitivity, metformin has a number of practical advantages over insulin:

- Potential weight loss or weight neutrality.^{37,48}
- Because of a lower risk of hypoglycemia, less frequent finger-stick BG measurements are required with metformin, compared with insulin therapy or sulfonylureas.^{37,42,49–51}
- Improves insulin sensitivity and may normalize menstrual cycles in females with polycystic ovary syndrome. (Because metformin may also improve fertility in patients with polycystic ovary syndrome, contraception is indicated for sexually active patients who wish to avoid pregnancy.)
- Taking pills does not have the discomfort associated with injections.
- Less instruction time is required to start oral medication, making it is easier for busy practitioners to prescribe.
- Adolescents do not always accept injections, so oral medication might enhance adherence.⁵²

Potential advantages of insulin over metformin for treatment at diabetes onset include the following:

- Metabolic control may be achieved more rapidly with insulin compared with metformin therapy.³⁷
- With appropriate education and targeting the regimen to the individual, adolescents are able to accept and use insulin therapy with improved metabolic outcomes.⁵³

- Insulin offers theoretical benefits of improved metabolic control while preserving β -cell function or even reversing β -cell damage.^{34,35}
- Initial use of insulin therapy may convey to the patient a sense of seriousness of the disease.^{7,53}

Throughout the writing of these guidelines, the authors have been following the progress of the National Institute of Diabetes and Digestive and Kidney Diseases–supported Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) trial,⁵⁴ designed to compare standard (metformin alone) therapy versus more aggressive therapy as the initial treatment of youth with recent-onset T2DM. Since the completion of these guidelines, results of the TODAY trial have become available and reveal that metformin alone is inadequate in effecting sustained glycemic control in the majority of youth with diabetes. The study also revealed that the addition of rosiglitazone to metformin is superior to metformin alone in preserving glycemic control. Direct application of these findings to clinical practice is problematic, however, because rosiglitazone is not FDA-approved for use in children, and its use, even in adults, is now severely restricted by the FDA because of serious adverse effects reported in adults. Thus, the results suggest that therapy that is more aggressive than metformin monotherapy may be required in these adolescents to prevent loss of glycemic control, but they do not provide specific guidance because it is not known whether the effect of the additional agent was specific to rosiglitazone or would be seen with the addition of other agents. Unfortunately, there are limited data for the use of other currently available oral or injected hypoglycemic agents in this age range, except for insulin. Therefore,

the writing group for these guidelines continues to recommend metformin as first-line therapy in this age group but with close monitoring for glycemic deterioration and the early addition of insulin or another pharmacologic agent if needed.

Lifestyle Modification, Including Nutrition and Physical Activity

Although lifestyle changes are considered indispensable to reaching treatment goals in diabetes, no significant data from RCTs provide information on success rates with such an approach alone.

A potential downside for initiating lifestyle changes alone at T2DM onset is potential loss of patients to follow-up and worse health outcomes. The value of lifestyle modification in the management of adolescents with T2DM is likely forthcoming after a more detailed analysis of the lifestyle intervention arm of the multicenter TODAY trial becomes available.⁵⁴ As noted previously, although it was published after

plus-rosiglitazone intervention in maintaining glycemic control over time.⁵⁴

Summary

As noted previously, metformin is a safe and effective agent for use at the time of diagnosis in conjunction with lifestyle changes. Although observational studies and expert opinion strongly support lifestyle changes as a key component of the regimen in addition to metformin, randomized trials are needed to delineate whether using lifestyle options alone is a reasonable first step in treating any select subgroups of children with T2DM.

Key Action Statement 3

The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for BG and HbA1c concentrations are not being met. (Option: evidence quality D; expert opinion and studies in children with T1DM and in adults with T2DM; preponderance of benefits over harms.)

Action Statement Profile KAS 3

Aggregate evidence quality	D (expert opinion and studies in children with T1DM and in adults with T2DM; no studies have been performed in children and adolescents with T2DM).
Benefit	Diminishing the risk of progression of disease and deterioration resulting in hospitalization; prevention of microvascular complications of T2DM.
Harm	Potential for hypoglycemia from overintensifying treatment to reach HbA1c target goals; cost of frequent testing and medical consultation; possible patient discomfort.
Benefits-harms assessment	Preponderance of benefits over harms.
Value judgments	Recommendation dictated by widely accepted standards of diabetic care.
Role of patient preferences	Minimal; recommendation dictated by widely accepted standards of diabetic care.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation as far as setting goals and intensifying treatment attributable to limited evidence.
Policy level	Option.

this guideline was developed, the TODAY trial indicated that results from the metformin-plus-lifestyle intervention were not significantly different from either metformin alone or the metformin-

HbA1c provides a measure of glycemic control in patients with diabetes mellitus and allows an estimation of the individual's average BG over the previous 8 to 12 weeks. No RCTs have

evaluated the relationship between glycemic control and the risk of developing microvascular and/or macrovascular complications in children and adolescents with T2DM. A number of studies of children with T1DM^{55–57} and adults with T2DM have, however, shown a significant relationship between glycemic control (as measured by HbA1c concentration) and the risk of microvascular complications (eg, retinopathy, nephropathy, and neuropathy).^{58,59} The relationship between HbA1c concentration and risk of microvascular complications appears to be curvilinear; the lower the HbA1c concentration, the lower the downstream risk of microvascular complications, with the greatest risk reduction seen at the highest HbA1c concentrations.⁵⁷

It is generally recommended that HbA1c concentrations be measured every 3 months.⁶⁰ For adults with T1DM, the American Diabetes Association recommends target HbA1c concentrations of less than 7%; the American Association of Clinical Endocrinologists recommends target concentrations of less than 6.5%. Although HbA1c target concentrations for children and adolescents with T1DM are higher,¹³ several review articles suggest target HbA1c concentrations of less than 7% for children and adolescents with T2DM.^{40,61–63} The committee concurs that, ideally, target HbA1c concentration should be less than 7% but notes that specific goals must be achievable for the individual patient and that this concentration may not be applicable for all patients. For patients in whom a target concentration of less than 7% seems unattainable, individualized goals should be set, with the ultimate goal of reaching guideline target concentrations. In addition, in the absence of hypoglycemia, even lower HbA1c target concentrations can be considered on the basis of an absence of hypoglycemic events and other individual considerations.

When concentrations are found to be above the target, therapy should be intensified whenever possible, with the goal of bringing the concentration to target. Intensification activities may include, but are not limited to, increasing the frequency of clinic visits, engaging in more frequent BG monitoring, adding 1 or more antidiabetic agents, meeting with a registered dietitian and/or diabetes educator, and increasing attention to diet and exercise regimens. Patients whose HbA1c concentrations remain relatively stable may only need to be tested every 6 months. Ideally, real-time HbA1c concentrations should be available at the time of the patient's visit with the clinician to allow the physician and patient and/or parent to discuss intensification of therapy during the visit, if needed.

Key Action Statement 4

The committee suggests that clinicians advise patients to monitor finger-stick BG concentrations in those who

- a. are taking insulin or other medications with a risk of hypoglycemia; or
- b. are initiating or changing their diabetes treatment regimen; or
- c. have not met treatment goals; or
- d. have intercurrent illnesses.

(Option: evidence quality D; expert consensus. Preponderance of benefits over harms.)

Glycemic control correlates closely with the frequency of BG monitoring in adolescents with T1DM.^{64,65} Although studies evaluating the efficacy of frequent BG monitoring have not been conducted in children and adolescents with T2DM, benefits have been described in insulin-treated adults with T2DM who tested their BG 4 times per day, compared with adults following a less frequent monitoring regimen.⁶⁶ These data support the value of BG monitoring in adults treated with insulin, and likely are relevant to youth with T2DM as well, especially those treated with insulin, at the onset of the disease, when treatment goals are not met, and when the treatment regimen is changed. The committee believes that current (2011) ADA recommendations for finger-stick BG monitoring apply to most youth with T2DM⁶⁷:

- Finger-stick BG monitoring should be performed 3 or more times daily for patients using multiple insulin injections or insulin pump therapy.
- For patients using less-frequent insulin injections, noninsulin therapies, or medical nutrition therapy alone, finger-stick BG monitoring may be useful as a guide to the success of therapy.
- To achieve postprandial glucose targets, postprandial finger-stick BG monitoring may be appropriate.

Recognizing that current practices may not always reflect optimal care, a 2004 survey of practices among members of the PES revealed that 36% of pediatric endocrinologists asked their pediatric patients with T2DM to monitor BG concentrations twice daily; 12% asked patients to do so once daily; 13% asked patients to do so 3 times per day; and 12% asked patients to do so 4 times daily.⁶¹ The questionnaire provided to the pediatric endocrinologists did not ask about the frequency of BG monitoring in relationship to the diabetes regimen, however.

Although normoglycemia may be difficult to achieve in adolescents with T2DM, a fasting BG concentration of 70 to 130 mg/dL is a reasonable target for most. In addition, because postprandial hyperglycemia has been associated with increased risk of cardiovascular events in adults, postprandial BG testing may be valuable in select patients. BG concentrations obtained 2 hours after meals (and paired with pre-meal concentrations) provide an index of glycemic excursion, and may be useful in improving glycemic control, particularly for the patient whose fasting plasma glucose is normal but whose HbA1c is not at target.⁶⁸ Recognizing the limited evidence for benefit of FSBG testing in this population, the committee provides suggested guidance for testing frequency, tailored to the medication regimen, as follows:

BG Testing Frequency for Patients With Newly Diagnosed T2DM: Fasting, Premeal, and Bedtime Testing

The committee suggests that all patients with newly diagnosed T2DM, regardless of prescribed treatment plan, should perform finger-stick BG monitoring before meals (including a morning fasting concentration) and

Action Statement Profile KAS 4

Aggregate evidence quality	D (expert consensus).
Benefit	Potential for improved metabolic control, improved potential for prevention of hypoglycemia, decreased long-term complications.
Harm	Patient discomfort, cost of materials.
Benefits-harms assessment	Benefit over harm.
Value judgments	Despite lack of evidence, there were general committee perceptions that patient safety concerns related to insulin use or clinical status outweighed any risks from monitoring.
Role of patient preferences	Moderate to low; recommendation driven primarily by safety concerns.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation about specific approaches attributable to lack of evidence and the need to individualize treatment.
Policy level	Option.

at bedtime until reasonable metabolic control is achieved.⁶⁹ Once BG concentrations are at target levels, the frequency of monitoring can be modified depending on the medication used, the regimen's intensity, and the patient's metabolic control. Patients who are prone to marked hyperglycemia or hypoglycemia or who are on a therapeutic regimen associated with increased risk of hypoglycemia will require continued frequent BG testing. Expectations for frequency and timing of BG monitoring should be clearly defined through shared goal-setting between the patient and clinician. The adolescent and family members should be given a written action plan stating the medication regimen, frequency and timing of expected BG monitoring, as well as follow-up instructions.

BG Testing Frequency for Patients on Single Insulin Daily Injections and Oral Agents

Single bedtime long-acting insulin: The simplest insulin regimen consists of a single injection of long-acting insulin at bedtime (basal insulin only). The appropriateness of the insulin dose for patients using this regimen is best defined by the fasting/prebreakfast BG test. For patients on this insulin regimen, the committee suggests daily fasting BG measurements. This regimen is associated with some risk of hypoglycemia (especially overnight or fasting hypoglycemia) and may not provide adequate insulin coverage for mealtime ingestions throughout the day, as reflected by fasting BG concentrations in target, but daytime readings above target. In such cases, treatment with meglitinide (Prandin [Novo Nordisk Pharmaceuticals] or Starlix [Novartis Pharmaceuticals]) or a short-acting insulin before meals (see below) may be beneficial.

Oral agents: Once treatment goals are met, the frequency of monitoring can be decreased; however, the committee recommends some continued BG testing for all youth with T2DM, at a frequency determined within the clinical context (e.g. medication regimen, HbA1c, willingness of the patient, etc.). For example, an infrequent or intermittent monitoring schedule may be adequate when the patient is using exclusively an oral agent associated with a low risk of hypoglycemia and if HbA1c concentrations are in the ideal or non-diabetic range. A more frequent monitoring schedule should be advised during times of illness or if symptoms of hyperglycemia or hypoglycemia develop.

Oral agent plus a single injection of a long-acting insulin: Some youth with T2DM can be managed successfully with a single injection of long-acting insulin in conjunction with an oral agent. Twice a day BG monitoring (fasting plus a second BG concentration – ideally 2-hour post prandial) often is recommended, as long as HbA1c and BG concentrations remain at goal and the patient remains asymptomatic.

BG Testing Frequency for Patients Receiving Multiple Daily Insulin Injections (eg, Basal Bolus Regimens): Premeal and Bedtime Testing

Basal bolus regimens are commonly used in children and youth with T1DM and may be appropriate for some youth with T2DM as well. They are the most labor intensive, providing both basal insulin plus bolus doses of short-acting insulin at meals. Basal insulin is provided through either the use of long-acting, relatively peak-free insulin (by needle) or via an insulin pump. Bolus insulin doses are given at meal-time, using one of the rapid-acting insulin analogs. The bolus dose is calculated by using a correction algorithm for the premeal BG concentration as well as a “carb ratio,” in which 1 unit of

a rapid-acting insulin analog is given for “X” grams of carbohydrates ingested (see box below). When using this method, the patient must be willing and able to count the number of grams of carbohydrates in the meal and divide by the assigned “carb ratio (X)” to know how many units of insulin should be taken. In addition, the patient must always check BG concentrations before the meal to determine how much additional insulin should be given as a correction dose using an algorithm assigned by the care team if the fasting BG is not in target. Insulin pumps are based on this concept of “basal-bolus” insulin administration and have the capability of calculating a suggested bolus dosage, based on inputted grams of carbohydrates and BG concentrations. Because the BG value determines the amount of insulin to be given at each meal, the recommended testing frequency for patients on this regimen is before every meal.

Box 1 Example of Basal Bolus Insulin Regimen

If an adolescent has a BG of 250 mg/dL, is to consume a meal containing 60 g of carbohydrates, with a carbohydrate ratio of 1:10 and an assigned correction dose of 1:25>125 (with 25 being the insulin sensitivity and 125 mg/dL the target blood glucose level), the mealtime bolus dose of insulin would be as follows:

60 g/10 “carb ratio” =

6 units rapid-acting insulin for meal

plus

(250–125)/25 = 125/25 =

5 units rapid-acting insulin for correction

Thus, total bolus insulin coverage at mealtime is: **11 U** (6 + 5) of rapid-acting insulin.

Key Action Statement 5

The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics’ *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in the nutrition counseling of

patients with T2DM both at the time of diagnosis and as part of ongoing management. (Option; evidence quality D; expert opinion; preponderance of benefits over harms. Role of patient preference is dominant.)

Action Statement Profile KAS 5

Aggregate evidence quality	D (expert opinion).
Benefit	Promotes weight loss; improves insulin sensitivity; contributes to glycemic control; prevents worsening of disease; facilitates a sense of well-being; and improves cardiovascular health.
Harm	Costs of nutrition counseling; inadequate reimbursement of clinicians’ time; lost opportunity costs vis-a-vis time and resources spent in other counseling activities.
Benefits-harms assessment	Benefit over harm.
Value judgments	There is a broad societal agreement on the benefits of dietary recommendations.
Role of patient preference	Dominant. Patients may have different preferences for how they wish to receive assistance in managing their weight-loss goals. Some patients may prefer a referral to a nutritionist while others might prefer accessing online sources of help. Patient preference should play a significant role in determining an appropriate weight-loss strategy.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation about specific approaches attributable to lack of evidence and the need to individualize treatment.
Policy level	Option.

Consuming more calories than one uses results in weight gain and is a major contributor to the increasing incidence of T2DM in children and adolescents. Current literature is inconclusive about a single best meal plan for patients with diabetes mellitus, however, and studies specifically addressing the diet of children and adolescents with T2DM are limited. Challenges to making recommendations stem from the small sample size of these studies, limited specificity for children and adolescents, and difficulties in generalizing the data from dietary research studies to the general population. Although evidence is lacking in children with T2DM, numerous studies have been conducted in overweight

children and adolescents, because the great majority of children with T2DM are obese or overweight at diagnosis.²⁶ The committee suggests that clinicians encourage children and adolescents with T2DM to follow the Academy of Nutrition and Dietetics’ recommendations for maintaining healthy weight to promote health and reduce obesity in this population. The committee recommends that clinicians refer patients to a registered dietitian who has expertise in the nutritional needs of youth with T2DM. Clinicians should incorporate the Academy of Nutrition and Dietetics’ *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines*, which describe effective, evidence-based treatment options for weight man-

agement, summarized below (A complete list of these recommendations is accessible to health care professionals at: <http://www.andevidencelibrary.com/topic.cfm?cat=4102&auth=1>.) According to the Academy of Nutrition and Dietetics’ guidelines, when incorporated with lifestyle changes, balanced macronutrient diets at 900 to 1200 kcal per day are associated with both short- and long-term (eg, ≥ 1 year) improvements in weight status and body composition in children 6 to 12 years of age.⁷⁰ These calorie recommendations are to be incorporated with lifestyle changes, including increased activity and possibly medication. Restrictions of no less than 1200 kcal per day in adolescents 13 to 18 years old result in improved weight status and body composition as well.⁷¹ The Diabetes Prevention Program demonstrated that participants assigned to the intensive lifestyle-intervention arm had a reduction in daily energy intake of 450 kcal and a 58% reduction in progression to diabetes at the 2.8-year follow-up.⁷¹ At the study’s end, 50% of the lifestyle-arm participants had achieved the goal weight loss of at least 7% after the 24-week curriculum and 38% showed weight loss of at least 7% at the time of their most recent visit.⁷² The Academy of Nutrition and Dietetics recommends that protein-sparing, modified-fast (ketogenic) diets be restricted to children who are >120% of their ideal body weight and who have a serious medical complication that would benefit from rapid weight loss.⁷¹ Specific recommendations are for the intervention to be short-term (typically 10 weeks) and to be conducted under the supervision of a multidisciplinary team specializing in pediatric obesity.

Regardless of the meal plan prescribed, some degree of nutrition education must be provided to maximize adherence and positive results. This education should encourage patients to follow healthy eating patterns, such as consuming 3 meals with planned snacks per day, not eating while watching television or using computers, using smaller plates to make portions appear larger, and leaving small amounts of food on the plate.⁷³ Common dietary recommendations to reduce calorie intake and to promote weight loss in children include the following: (1) eating regular meals and snacks; (2) reducing portion sizes; (3) choosing calorie-free beverages, except for milk; (4) limiting juice to 1 cup per day; (5) increasing consumption of fruits and vegetables; (6) consuming 3 or 4 servings of low-fat dairy products per day; (7) limiting intake of high-fat foods; (8) limiting frequency and size of snacks; and (9) reducing calories consumed in fast-food meals.⁷⁴

Key Action Statement 6

The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic screen time to

less than 2 hours per day. (Option: evidence quality D, expert opinion and evidence from studies of metabolic syndrome and obesity; preponderance of benefits over harms. Role of patient preference is dominant.)

Action Statement Profile KAS 6

Aggregate evidence quality	D (expert opinion and evidence from studies of metabolic syndrome and obesity).
Benefit	Promotes weight loss; contributes to glycemic control; prevents worsening of disease; facilitates the ability to perform exercise; improves the person's sense of well-being; and fosters cardiovascular health.
Harm	Cost for patient of counseling, food, and time; costs for clinician in taking away time that could be spent on other activities; inadequate reimbursement for clinician's time.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Broad consensus.
Role of patient preference	Dominant. Patients may seek various forms of exercise. Patient preference should play a significant role in creating an exercise plan.
Exclusions	Although certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely, this recommendation applies to the vast majority of children and adolescents with T2DM.
Intentional vagueness	Intentional vagueness on the sequence of follow-up contact attributable to the lack of evidence and the need to individualize care.
Policy level	Option.

Recommendations From the Academy of Nutrition and Dietetics

Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines

Recommendation	Strength
Interventions to reduce pediatric obesity should be multicomponent and include diet, physical activity, nutritional counseling, and parent or caregiver participation.	Strong
A nutrition prescription should be formulated as part of the dietary intervention in a multicomponent pediatric weight management program.	Strong
Dietary factors that may be associated with an increased risk of overweight are increased total dietary fat intake and increased intake of calorically sweetened beverages.	Strong
Dietary factors that may be associated with a decreased risk of overweight are increased fruit and vegetable intake.	Strong
A balanced macronutrient diet that contains no fewer than 900 kcal per day is recommended to improve weight status in children aged 6–12 y who are medically monitored.	Strong
A balanced macronutrient diet that contains no fewer than 1200 kcal per day is recommended to improve weight status in adolescents aged 13–18 y who are medically monitored.	Strong
Family diet behaviors that are associated with an increased risk of pediatric obesity are parental restriction of highly palatable foods, consumption of food away from home, increased meal portion size, and skipping breakfast.	Fair

Engaging in Physical Activity

Physical activity is an integral part of weight management for prevention and treatment of T2DM. Although there is a paucity of available data from children and adolescents with T2DM, several well-controlled studies performed in obese children and adolescents at risk of metabolic syndrome and T2DM provide guidelines for physical activity. (See the Resources section for tools on this subject.) A summary of the references supporting the evidence for this guideline can be found in the technical report.³¹

At present, moderate-to-vigorous exercise of at least 60 minutes daily is recommended for reduction of BMI and improved glycemic control in patients with T2DM.⁷⁵ “Moderate to

vigorous exercise” is defined as exercise that makes the individual breathe hard and perspire and that raises his or her heart rate. An easy way to define exercise intensity for patients is the “talk test”; during moderate physical activity a person can talk but not sing. During vigorous activity, a person cannot talk without pausing to catch a breath.⁷⁶

Adherence may be improved if clinicians provide the patient with a written prescription to engage in physical activity, including a “dose” describing ideal duration, intensity, and frequency.⁷⁵ When prescribing physical exercise, clinicians are encouraged to be sensitive to the needs of children, adolescents, and their families. Routine, organized exercise may be beyond the family’s logistical and/or financial means, and some families may not be able to provide structured exercise programs for their children. It is most helpful to recommend an individualized approach that can be incorporated into the daily routine, is tailored to the patients’ physical abilities and preferences, and recognizes the families’ circumstances.⁷⁷ For example, clinicians might recommend only daily walking, which has been shown to improve weight loss and insulin sensitivity in adults with T2DM⁷⁸ and may constitute “moderate to vigorous activity” for some children with T2DM. It is also important to recognize that the recommended 60 minutes of exercise do not have to be accomplished in 1 session but can be completed through several, shorter increments (eg, 10–15 minutes). Patients should be encouraged to identify a variety of forms of activity that can be performed both easily and frequently.⁷⁷ In addition, providers should be cognizant of the potential need to adjust the medication dosage, especially if the patient is receiving insulin, when initiating an aggressive physical activity program.

Reducing Screen Time

Screen time contributes to a sedentary lifestyle, especially when the child or adolescent eats while watching television or playing computer games. The US Department of Health and Human Services recommends that individuals limit “screen time” spent watching television and/or using computers and handheld devices to less than 2 hours per day unless the use is related to work or homework.⁷⁹ Physical activity may be gained either through structured games and sports or through everyday activities, such as walking, ideally with involvement of the parents as good role models.

Increased screen time and food intake and reduced physical activity are associated with obesity. There is good evidence that modifying these factors can help prevent T2DM by reducing the individual’s rate of weight gain. The evidence profile in pediatric patients with T2DM is inadequate at this time, however. Pending new data, the committee suggests that clinicians follow the AAP Committee on Nutrition’s guideline, *Prevention of Pediatric Overweight and Obesity*. The guideline recommends restricting nonacademic screen time to a maximum of 2 hours per day and discouraging the presence of video screens and television sets in children’s bedrooms.^{80–82} The American Medical Association’s Expert Panel on Childhood Obesity has endorsed this guideline.

Valuable recommendations for enhancing patient health include the following:

- With patients and their families, jointly determining an individualized plan that includes specific goals to reduce sedentary behaviors and increase physical activity.
- Providing a written prescription for engaging in 60-plus minutes of moderate-to-vigorous physical activities per day that includes

dose, timing, and duration. It is important for clinicians to be sensitive to the needs of children, adolescents, and their families in encouraging daily physical exercise. Graded duration of exercise is recommended for those youth who cannot initially be active for 60 minutes daily, and the exercise may be accomplished through several, shorter increments (eg, 10–15 minutes).

- Incorporating physical activities into children’s and adolescents’ daily routines. Physical activity may be gained either through structured games and sports or through everyday activities, such as walking.
- Restricting nonacademic screen time to a maximum of 2 hours per day.
- Discouraging the presence of video screens and television sets in children’s bedrooms.

Conversations pertaining to the Key Action Statements should be clearly documented in the patient’s medical record.

AREAS FOR FUTURE RESEARCH

As noted previously, evidence for medical interventions in children in general is scant and is especially lacking for interventions directed toward children who have developed diseases not previously seen commonly in youth, such as childhood T2DM. Recent studies such as the Search for Diabetes in Youth Study (SEARCH)—an observational multicenter study in 2096 youth with T2DM funded by the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases—now provide a detailed description of childhood diabetes. Subsequent trials will describe the short-term and enduring effects of specific interventions

on the progression of the disease with time.

Although it is likely that children and adolescents with T2DM have an aggressive form of diabetes, as reflected by the age of onset, future research should determine whether the associated comorbidities and complications of diabetes also are more aggressive in pediatric populations than in adults and if they are more or less responsive to therapeutic interventions. Additional research should explore whether early introduction of insulin or the use of particular oral agents will preserve β -cell function in these children, and whether recent technologic advances (such as continuous glucose monitoring and insulin pumps) will benefit this population. Additional issues that require further study include the following:

- To delineate whether using lifestyle options without medication is a reliable first step in treating selected children with T2DM.
- To determine whether BG monitoring should be recommended to all children and youth with T2DM, regardless of therapy used; what the optimal frequency of BG monitoring is for pediatric patients on the basis of treatment regimen; and which subgroups will be able to successfully maintain glycemic goals with less frequent monitoring.
- To explore the efficacy of school- and clinic-based diet and physical activity interventions to prevent and manage pediatric T2DM.
- To explore the association between increased “screen time” and reduced physical activity with respect to T2DM’s risk factors.

RESOURCES

Several tools are available online to assist providers in improving patient

adherence to lifestyle modifications, including examples of activities to be recommended for patients:

- The American Academy of Pediatrics:
 - www.healthychildren.org
 - www.letsmove.gov
 - Technical Report: Management of Type 2 Diabetes Mellitus in Children and Adolescents.⁵¹
 - Includes an overview and screening tools for a variety of comorbidities.
 - Gahagan S, Silverstein J; Committee on Native American Child Health and Section on Endocrinology. Clinical report: prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native Children. *Pediatrics*. 2003;112(4):e328–e347. Available at: <http://www.pediatrics.org/cgi/content/full/112/4/e328>⁶³
 - Fig 3 presents a screening tool for microalbumin.
 - Bright Futures: <http://brightfutures.aap.org/>
 - Daniels SR, Greer FR; Committee on Nutrition. Lipid screening and cardiovascular health in childhood. *Pediatrics*. 2008;122(1):198–208. Available at:
- The American Diabetes Association: www.diabetes.org
 - Management of dyslipidemia in children and adolescents with diabetes. *Diabetes Care*. 2003;26(7):2194–2197. Available at: <http://care.diabetesjournals.org/content/26/7/2194.full>
- Academy of Nutrition and Dietetics:
 - <http://www.eatright.org/childhoodobesity/>
 - <http://www.eatright.org/kids/>
 - <http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/index.html>
- Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines: <http://www.adaevidencelibrary.com/topic.cfm?cat=2721>
- American Heart Association:
 - American Heart Association *Circulation*. 2006 Dec 12;114(24):2710–2738. Epub 2006 Nov 27. Review.
- Centers for Disease Control and Prevention:
 - <http://www.cdc.gov/obesity/childhood/solutions.html>
 - BMI and other growth charts can be downloaded and printed from the CDC Web site: <http://www.cdc.gov/growth-charts>.
 - Center for Epidemiologic Studies Depression Scale (CES-D): <http://www.chcr.brown.edu/pcoc/cesdscale.pdf>; see attachments
- *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed. Washington, DC: American Psychiatric Association; 1994
- Let’s Move Campaign: www.letsmove.gov
- The Reach Institute. *Guidelines for Adolescent Depression in Primary Care (GLAD-PC) Toolkit*, 2007. Contains a listing of the criteria for major depressive disorder as defined by the DSM-IV-TR. Available at: <http://www.gladpc.org>
- The National Heart, Lung, and Blood Institute (NHLBI) hypertension guidelines: http://www.nhlbi.nih.gov/guidelines/hypertension/child_tbl.htm
- The National Diabetes Education Program and TIP sheets (including tip sheets on youth transitioning to adulthood and adult providers, Staying Active, Eating Healthy, Ups and Downs of Diabetes, etc): www.ndep.nih.gov or www.yourdiabetesinfo.org

- National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents: *Pediatrics*. 2004;114:555–576. Available at: http://pediatrics.aappublications.org/content/114/Supplement_2/555.long
- National Initiative for Children's Healthcare Quality (NICHQ): childhood obesity section: http://www.nichq.org/childhood_obesity/index.html
- The National Institute of Child Health and Human Development (NICHD): www.NICHD.org
- President's Council on Physical Fitness and Sports: http://www.presidentschallenge.org/home_kids.aspx
- US Department of Agriculture's "My Pyramid" Web site:

- <http://www.choosemyplate.gov/>
- <http://fnic.nal.usda.gov/life-cycle-nutrition/child-nutrition-and-health>

SUBCOMMITTEE ON TYPE 2 DIABETES (OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2008–2012)

Kenneth Claud Copeland, MD, FAAP: Co-chair—Endocrinology and Pediatric Endocrine Society Liaison (2009: Novo Nordisk, Genentech, Endo [National Advisory Groups]; 2010: Novo Nordisk [National Advisory Group]); published research related to type 2 diabetes

Janet Silverstein, MD, FAAP: Co-chair—Endocrinology and American Diabetes Association Liaison (small grants with Pfizer, Novo Nordisk, and Lilly; grant review committee for Genentech; was on an advisory committee for Sanofi Aventis, and Abbott Laboratories for a 1-time meeting); published research related to type 2 diabetes

Kelly Roberta Moore, MD, FAAP: General Pediatrics, Indian Health, AAP Committee on Native American Child Health Liaison (board member of the Merck Company Foundation

Alliance to Reduce Disparities in Diabetes. Their national program office is the University of Michigan's Center for Managing Chronic Disease.)

Greg Edward Prazar, MD, FAAP: General Pediatrics (no conflicts)

Terry Raymer, MD, CDE: Family Medicine, Indian Health Service (no conflicts)

Richard N. Shiffman, MD, FAAP: Partnership for Policy Implementation Informatician, General Pediatrics (no conflicts)

Shelley C. Springer, MD, MBA, FAAP: Epidemiologist (no conflicts)

Meaghan Anderson, MS, RD, LD, CDE: Academy of Nutrition and Dietetics Liaison (formerly a Certified Pump Trainer for Animas)

Stephen J. Spann, MD, MBA, FAAP: American Academy of Family Physicians Liaison (no conflicts)

Vidhu V. Thaker, MD, FAAP: Qulin Liaison, General Pediatrics (no conflicts)

CONSULTANT

Susan K. Flinn, MA: Medical Writer (no conflicts)

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ERRATA

Several inaccuracies occurred in the American Academy of Pediatrics “Clinical Practice Guideline: Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents” published in the February 2013 issue of *Pediatrics* (2013;131[2]:364–382).

On page 366 in the table of definitions, “Prediabetes” should be defined as “Fasting plasma glucose ≥ 100 –125 mg/dL or 2-hour glucose concentration during an oral glucose tolerance test of ≥ 140 but < 200 mg/dL or an HbA1c of 5.7% to 6.4%.”

On page 378, middle column, under “Reducing Screen Time,” the second sentence should read as follows: “The US Department of Health and Human Services reflects the American Academy of Pediatrics policies by recommending that individuals limit “screen time” spent watching television and/or using computers and handheld devices to < 2 hours per day unless the use is related to work or homework.”^{79–81,83}

Also on page 378, middle column, in the second paragraph under “Reducing Screen Time,” the fourth sentence should read: “Pending new data, the committee suggests that clinicians follow the policy statement ‘Children, Adolescents, and Television’ from the AAP Council on Communications and Media (formerly the Committee on Public Education).” The references cited in the next sentence should be 80–83.

Reference 82 should be replaced with the following reference: Barlow SE; Expert Committee. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics*. 2007;120(suppl 4):S164–S192

Finally, a new reference 83 should be added: American Academy of Pediatrics, Council on Communications and Media. Policy statement: children, adolescents, obesity, and the media. *Pediatrics*. 2011;128(1):201–208

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TECHNICAL REPORT

Management of Type 2 Diabetes Mellitus in Children and Adolescents

abstract



OBJECTIVE: Over the last 3 decades, the prevalence of childhood obesity has increased dramatically in North America, ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. This technical report describes, in detail, the procedures undertaken to develop the recommendations given in the accompanying clinical practice guideline, “Management of Type 2 Diabetes Mellitus in Children and Adolescents,” and provides in-depth information about the rationale for the recommendations and the studies used to make the clinical practice guideline’s recommendations.

METHODS: A primary literature search was conducted relating to the treatment of T2DM in children and adolescents, and a secondary literature search was conducted relating to the screening and treatment of T2DM’s comorbidities in children and adolescents. Inclusion criteria were prospectively and unanimously agreed on by members of the committee. An article was eligible for inclusion if it addressed treatment (primary search) or 1 of 4 comorbidities (secondary search) of T2DM, was published in 1990 or later, was written in English, and included an abstract. Only primary research inquiries were considered; review articles were considered if they included primary data or opinion. The research population had to constitute children and/or adolescents with an existing diagnosis of T2DM; studies of adult patients were considered if at least 10% of the study population was younger than 35 years. All retrieved titles, abstracts, and articles were reviewed by the consulting epidemiologist.

RESULTS: Thousands of articles were retrieved and considered in both searches on the basis of the aforementioned criteria. From those, in the primary search, 199 abstracts were identified for possible inclusion, 58 of which were retained for systematic review. Five of these studies were classified as grade A studies, 1 as grade B, 20 as grade C, and 32 as grade D. Articles regarding treatment of T2DM selected for inclusion were divided into 4 major subcategories on the basis of type of treatment being discussed: (1) medical treatments (32 studies); (2) nonmedical treatments (9 studies); (3) provider behaviors (8 studies); and (4) social issues (9 studies). From the secondary search, an additional 336 abstracts relating to comorbidities were identified for possible inclusion, of which 26 were retained for systematic review. These articles included the following: 1 systematic review of literature regarding comorbidities of T2DM in adolescents; 5 expert

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KEY WORDS

childhood, clinical practice guidelines, comanagement, diabetes, management, treatment, type 2 diabetes mellitus, youth

ABBREVIATIONS

AAP—American Academy of Pediatrics
ACE—angiotensin-converting enzyme
ADA—American Diabetes Association
AHA—American Heart Association
BG—blood glucose
CAM—complementary and alternative medicine
CES-D—Center for Epidemiologic Studies Depression Scale
CVD—cardiovascular disease
HbA1c—hemoglobin A1c
LDL-C—low-density lipoprotein cholesterol
PCP—primary care provider
QDS—Quality Data Set
RCT—randomized controlled trial
T1DM—type 1 diabetes mellitus
T2DM—type 2 diabetes mellitus

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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opinions presenting global recommendations not based on evidence; 5 cohort studies reporting natural history of disease and comorbidities; 3 with specific attention to comorbidity patterns in specific ethnic groups (case-control, cohort, and clinical report using adult literature); 3 reporting an association between microalbuminuria and retinopathy (2 case-control, 1 cohort); 3 reporting the prevalence of nephropathy (cohort); 1 reporting peripheral vascular disease (case series); 2 discussing retinopathy (1 case-control, 1 position statement); and 3 addressing hyperlipidemia (American Heart Association position statement on cardiovascular risks; American Diabetes Association consensus statement; case series). A breakdown of grade of recommendation shows no grade A studies, 10 grade B studies, 6 grade C studies, and 10 grade D studies. With regard to screening and treatment recommendations for comorbidities, data in children are scarce, and the available literature is conflicting. Therapeutic recommendations for hypertension, dyslipidemia, retinopathy, microalbuminuria, and depression were summarized from expert guideline documents and are presented in detail in the guideline. The references are provided, but the committee did not independently assess the supporting evidence. Screening tools are provided in the Supplemental Information. *Pediatrics* 2013;131:e648–e664

INTRODUCTION

This technical report details the procedures undertaken to develop the recommendations given in the accompanying clinical practice guideline, “Management of Type 2 Diabetes Mellitus in Children and Adolescents.” What follows is a description of the process, including the committee’s objectives; methods of evidence identification, retrieval, review, and analysis; and summaries of the committee’s conclusions.

Statement of the Issue

Over the last 3 decades, type 2 diabetes mellitus (T2DM), a disease previously confined to adult patients, has markedly increased in prevalence among children and adolescents. Currently, in the United States, approximately 1 in 3 new cases of diabetes mellitus diagnosed in patients younger than 18 years is T2DM,^{1,2} with a disproportionate representation in ethnic minorities,^{3,4} especially among adolescents.⁵ This trend is not limited to the United States but is occurring internationally as well.⁶

The rapid emergence of childhood T2DM poses challenges to the physician who is unequipped to treat adult diseases encountered in children. Most diabetes training and educational materials designed for pediatric patients address type 1 diabetes mellitus (T1DM) and emphasize insulin treatment and glucose

monitoring, which may or may not be appropriate for children with T2DM.^{7,8} Most medications used for T2DM have been tested for safety and efficacy only in individuals older than 18 years, and there is scant scientific evidence for optimal management of children with T2DM.^{9,10} Extrapolation of data from adult studies to pediatric populations may not be valid because the hormonal milieu of the prepubescent and pubescent patient with T2DM can affect treatment goals and modalities in ways heretofore unencountered in adult patients.¹¹

The United States has a severe shortage of pediatric endocrinologists, making access to these specialists difficult or, in some cases, impossible.¹² Vast geographic areas lack a pediatric endocrinologist: in 2011, 3 states had no pediatric endocrinologists, and 22 had fewer than 10, and the situation is unlikely to improve in the near future.¹³ In 2004, the National Association of Children’s Hospitals and Related Institutions performed a workforce survey and found that patients had to wait almost 9 weeks for an appointment to see an endocrinologist.¹⁴ Because the number of patients with T1DM and T2DM has increased since then, this situation is presumably worse today. Regardless of their age, most patients in the United States who have T2DM are cared for by primary care providers (PCPs).¹⁵

Furthermore, given the expected increases in the national and global incidence of T2DM and the near impossibility that the pediatric endocrine workforce will increase proportionately, PCPs must be prepared for and capable of managing children and adolescents who have uncomplicated T2DM.

Numerous experts have argued that the ideal care of a child with T2DM is provided through a team approach, with care shared among a pediatric endocrinologist, diabetes nurse educator, nutritionist, and behavioral specialist.^{16–18} In areas of limited access to pediatric endocrinologists, however, contact with the pediatric endocrinology team might involve contact at diagnosis for initial diabetes education and intermittently thereafter; annually, with interval care by a PCP and interval communication with the pediatric endocrinology team; or at every visit, for those patients who are either doing poorly or are taking insulin.

In areas where access to subspecialists is hampered by geographic distances and/or professional shortages, care provided by local generalists who are skilled in treating children and youth with T2DM is likely to improve access to medical care. Although there are no pediatric studies evaluating this issue, the committee believes that this improved access to care might result in:

- Reduced wait times and increased timeliness of care.
- Reduced economic burden to the patient, including reduced need to travel and reduced time lost from work and/or school.
- Potentially improved patient retention. Kawahara et al¹⁹ reported that 56.9% of patients with T2DM stopped coming to their hospital diabetes clinic appointments, most commonly because they were “too busy” to keep their appointments.

Recent advances in medical technology have the potential to ameliorate limited access to specialists. Reporting on the provision of clinical specialty diabetes care to remote locations using telemedicine, Malasanos et al²⁰ found that weekly telemedicine clinics were able to effectively replace quarterly face-to-face clinics after an initial face-to-face clinic visit. This more frequent contact provided by the telemedicine clinics resulted in improved hemoglobin A1c (HbA1c) concentrations, better patient satisfaction, fewer days missed from work or school, more time spent with the patient during clinic visits, and fewer subsequent hospitalizations and emergency department visits. Telemedicine is costly, however, and requires equipment to be in place at both the subspecialist's office and the remote clinic; it is, therefore, not appropriate for every practice. It is possible that a similar model of service could be provided by a generalist working locally and in close communication with a specialist.

For family physicians and others who care for adult patients, managing T2DM in children poses potential challenges. The first is that what works for adults may not work for children. Experiences and results observed in adults do not necessarily apply to children. Children (and even adolescents) are not small adults; they have a changing hormonal

environment, have differences in physiology, and their growth can have effects on medication doses, toxicity, and responses.¹¹ As a result, generalists who are confident in caring for adults with diabetes may attempt to apply adult practice experiences to children, in whom these may not necessarily be appropriate. Kaufman cited data on various drugs' effects in children and argued that harm may occur if children with T2DM are treated like adults with T2DM.¹¹ The author called for treatment trials for children with T2DM, to “better define the risk-benefit ratio in children and youth, since this may differ substantially from that in the adult type 2 diabetic population.” In contrast, others have noted that most adolescents with T2DM are similar to adults in terms of size and reproductive maturity and argued that, in the absence of studies specifically targeted to adolescents, treatment regimens can be extrapolated from studies of adults with T2DM; they do agree, however, that more randomized controlled trials (RCTs) are needed in the pediatric population.¹

A second challenge is presented by the conflicting evidence regarding outcomes in patients with diabetes who are managed by generalists versus subspecialists. Some studies in adult patients indicate that generalists are capable of achieving outcomes similar to those of subspecialists. Greenfield et al²¹ observed that physiologic and functional status (ie, physical, psychological, social functioning) were similar at both 2 and 4 years and mortality was similar at 7 years in adult hypertensive patients with diabetes treated in multispecialty groups versus health maintenance organization general practices. Other studies indicate that generalists may achieve outcomes similar to those of diabetes specialists, as long as they have input from subspecialists.

Indeed, unlike diseases in several other specialties, care for children with diabetes that is conducted by generalists without input from specialists may be inferior to that provided by specialists. Ziener et al²² used an RCT design to examine the effect of providing 5 minutes of direct feedback from an endocrinologist to a PCP every 2 weeks. Performance in the feedback group was sustained after 3 years, and performance decayed in a comparison group that received computer-generated decision support reminders, including a flow-sheet section showing previous clinical data and a recommendations section. Specialist feedback contributed independently to intensification of diabetes management. In addition, “clinical inertia” (defined as failure by providers to intensify pharmacologic therapy for hyperglycemia) was more likely in a primary care versus a diabetes clinic setting (91% vs 52%) and resulted in higher HbA1c concentrations among patients.²³

How these observations might be applied to the child who has T2DM is not entirely clear, but they suggest that regular, direct contact between the generalist and a specialist can have a positive outcome on these patients. De Berardis et al²⁴ reported that, compared with adult patients with diabetes mellitus who were seen in general practice offices, patients cared for in diabetes clinics were more likely to conform with process-of-care measures, including HbA1c concentrations, blood pressure, total cholesterol and low-density lipoprotein cholesterol (LDL-C) levels, microalbuminuria testing, and foot and eye examinations and were more likely to have adequate concentrations of total cholesterol. No differences were found in glycemic, blood pressure, or LDL-C control, however. In that same study, all process-of-care measures improved when the patient was seen by a single physician

as opposed to being seen by several different physicians. No similar studies have been performed in children, and it is therefore unknown whether similar outcomes can be achieved in the pediatric population.

A third challenge is presented by the fact that children with T2DM are overrepresented among racial and ethnic minority populations and are more likely to be living in poverty; therefore, they may face significant challenges in accessing specialists, even under the best situations.²⁵ Recognizing these barriers to care and patients' real-world needs, it is the committee's consensus that it is impractical to expect every patient with T2DM to be able to access a pediatric endocrinologist on a regular basis. It is also unreasonable to assume that these visits will be frequent enough to provide the level of care needed to maintain the best possible metabolic control. For this reason alone, PCPs must have a thorough knowledge of the management of T2DM, including its unique aspects related to childhood and adolescence.

The committee also believes it is the PCP's responsibility to obtain the requisite skills for such care and to communicate and work closely with a diabetes team of subspecialists whenever possible. For this reason, when treatment goals are not met, the committee encourages clinicians to consult with an expert trained in the care of children and adolescents with T2DM. When first-line therapy fails (eg, metformin), recommendations for intensifying therapy should be generally the same for pediatric and adult populations. The picture is constantly changing, however, as new drugs are being introduced, and some drugs that initially seemed to be safe exhibit adverse effects with wider use. Clinicians should, therefore, remain alert to new developments in this area. Seeking the advice of an expert can help ensure that the treatment goals are

appropriately set and that clinicians benefit from cutting-edge treatment information in this rapidly changing area.

Stated Objective of the American Academy of Pediatrics

Because the PCP caring for children will likely encounter T2DM, the American Academy of Pediatrics (AAP), the Pediatric Endocrine Society, the American Academy of Family Physicians, the American Diabetes Association (ADA), and the American Dietetic Association undertook a cooperative effort to develop clinical guidelines for the treatment of T2DM in children and adolescents, for the benefit of subspecialists and generalists alike. Representatives from these groups collaborated on developing an evidence profile that served as a major source of information for the accompanying clinical practice guideline recommendations. This report, based on a review of the current medical literature covering a period from January 1, 1990, to July 1, 2009, provides a set of evidence-based guidelines for the management and treatment of T2DM in children and adolescents.

It should be noted that, because childhood T2DM is a relatively recent medical phenomenon, there is a paucity of evidence for many or most of the recommendations provided in the accompanying guideline. Committee members have made every effort to demarcate in the guideline those references that were not identified in the original literature search and are not included in this technical report. Although provided for the reader's information, these references not identified in the literature search did not affect or alter the level of evidence for specific recommendations.

Composition of the Committee

The ad hoc multidisciplinary committee was cochaired by 2 pediatric endocrinologists pre-eminent in their

field and included experts in general pediatrics, family medicine, nutrition, Native American health, epidemiology, and medical informatics. All panel members reviewed the AAP Policy on Conflict of Interest and Voluntary Disclosure and declared all potential conflicts.

Definitions

- Children and adolescents: patients ≥ 10 and ≥ 18 years of age.
- Childhood T2DM: disease in the child who typically: is obese (BMI ≥ 85 th to 94th percentile and >95 th percentile for age and gender, respectively); has a strong family history of T2DM; has substantial residual insulin secretory capacity at diagnosis (reflected by normal or elevated insulin and C-peptide concentrations); has insidious onset of disease; demonstrates insulin resistance (including clinical evidence of polycystic ovarian syndrome or acanthosis nigricans); and lacks evidence of diabetic autoimmunity. These patients are more likely to have hypertension and dyslipidemia than those with T1DM.
- Hyperglycemia: definition as accepted by the ADA. Specifically: fasting blood glucose (BG) concentration >126 mg/dL, random or 2-hour post-Glucola (Ames Co, Elkhart, IN) BG concentration >200 mg/dL.
- Clinician: any provider within his or her scope of practice; includes medical practitioners (including physicians and physician extenders), dietitians, psychologists, and nurses.
- Comorbidities: specifically limited to cardiovascular disease (CVD), hypertension, dyslipidemias and hypercholesterolemias, atherosclerosis, peripheral neuropathy, retinopathy, and nephropathy (microvascular and macrovascular). Obesity was considered a prediabetic condition and was specifically excluded.

- Diabetes: according to the ADA criteria, defined as:

1. HbA1c concentration $\geq 6.5\%$ (test performed in an appropriately certified laboratory); or
2. Fasting (defined as no caloric intake for at least 8 hours) plasma glucose concentration ≥ 126 mg/dL (7.0 mmol/L); or
3. Two-hour plasma glucose concentration ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (test performed as described by the World Health Organization by using a glucose load containing the equivalent of 75 g of anhydrous glucose dissolved in water); or
4. A random plasma glucose concentration ≥ 200 mg/dL (11.1 mmol/L) with symptoms of hyperglycemia.

(In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.)

- Diabetic ketoacidosis: the absolute or relative insulin deficiency resulting in fat breakdown with resultant formation of β -hydroxybutyrate and accompanying acidosis. Symptoms include nausea, vomiting, Kussmaul respirations, dehydration, and altered mental status.
- Fasting BG: BG concentration obtained before the first meal of the day and after a fast of at least 8 hours.
- Glucose toxicity: the effect of high BG causing both insulin resistance and impaired β -cell production of insulin.
- Intensification: increasing frequency of BG monitoring and adjustment of the dose and type of medication to decrease BG concentrations.
- Intercurrent illnesses: febrile illnesses or associated symptoms severe enough to cause the patient

to stay home from school and/or seek medical care.

- Microalbuminuria: albumin-to-creatinine ratio ≥ 30 mg/g creatinine but < 300 mg/g creatinine.
- Moderate hyperglycemia: BG concentration of 180 to 250 mg/dL.
- Moderate to vigorous exercise: exercise that makes the individual breathe hard and perspire and which raises his or her heart rate. An easy way to define exercise intensity for patients is the “talk test”: during moderate physical activity a person can talk but not sing. During vigorous activity, a person cannot talk without pausing to catch a breath.
- Obese: BMI ≥ 95 th percentile for age and gender.
- Overweight: BMI between 85th and 94th percentile for age and gender.
- Prediabetes: Fasting plasma glucose concentration ≥ 100 to 125 mg/dL or 2-hour glucose concentration during an oral glucose tolerance test ≥ 126 mg/dL but < 200 mg/dL or HbA1c of 5.7% to 6.4%.
- Severe hyperglycemia: BG concentration > 250 mg/dL.
- Thiazolidinediones: oral hypoglycemic agents that exert their effect at least in part by activation of the peroxisome proliferator-activated receptor- γ .
- T1DM: diabetes secondary to autoimmune destruction of β -cells resulting in absolute (complete or near complete) insulin deficiency and requiring insulin injections for management.
- T2DM: The investigators’ designation of the diagnosis was used for the purposes of the literature review. The committee acknowledges that the distinction between T1DM and T2DM in this population is not always clear-cut, and clinical

judgment plays an important role. Typically, this diagnosis is made when hyperglycemia is secondary to insulin resistance accompanied by impaired β -cell function, resulting in inadequate insulin production to compensate for the degree of insulin resistance.

- Youth: used interchangeably with “adolescent” in this document.

FORMULATION AND ARTICULATION OF THE QUESTION ADDRESSED BY THE COMMITTEE

The committee first formulated explicit questions for which evidence would be queried by the epidemiologist. Specific clinical questions addressed by the committee included: (1) the effectiveness of treatment modalities for T2DM in children and adolescents; (2) the efficacy of pharmaceutical therapies for treatment of children and adolescents with T2DM; (3) appropriate recommendations for screening for comorbidities typically associated with T2DM in children and adolescents; and (4) treatment recommendations for comorbidities of T2DM in children and adolescents.

These recommendations pertain specifically to patients at least 10 but younger than 18 years of age with T2DM. Although the distinction between T1DM and T2DM in children may be difficult,^{26,27} for purposes of this report, the definition of childhood T2DM includes the child who typically is overweight or obese (defined as having a BMI ≥ 85 th to 94th percentile and > 95 th percentile for age and gender, respectively); has a strong family history of T2DM; has substantial residual insulin secretory capacity at diagnosis (reflected by normal or elevated insulin and C-peptide concentrations); has insidious onset of disease; demonstrates insulin resistance (including clinical evidence of polycystic ovarian syndrome or acanthosis nigricans); and lacks

evidence of diabetic autoimmunity (negative for autoantibodies typically associated with T1DM). Patients with T2DM are more likely to have hypertension and dyslipidemia than are those with T1DM.

Methods

Primary Literature Search: Treatment of T2DM

The committee unanimously agreed on the objectives of the guideline and scope of the evidence search. A primary literature search was conducted by the consulting epidemiologist, using the strategy as described in the following text.

An article was eligible for inclusion if it addressed treatment of T2DM, was published in 1990 or later, was written in English, and included an abstract. Only primary research inquiries were considered; review articles were considered if they included primary data or opinion. Children and/or adolescents with an existing diagnosis of T2DM were required to constitute the research population; studies of adult patients were considered if $\geq 10\%$ of their population was younger than 35 years.

The electronic databases PubMed, Cochrane Collaboration, and Embase were searched using the following Medical Subject Headings, alone and in various combinations: diabetes, mellitus, type 2, type 1, treatment, prevention, insipidus, diet, pediatric, T2DM, T1DM, non-insulin dependent diabetes mellitus (NIDDM), metformin, lifestyle, RCT, meta-analysis, child, adolescent, therapeutics, control, adult, obese, gestational, polycystic ovary syndrome, metabolic syndrome, cardiovascular, dyslipidemia, men, and women. In addition, the Boolean operators NOT, AND, and OR were used with the aforementioned terms, also in various combinations. Search limits included clinical trial, meta-analysis, randomized controlled trial, review, child: 6–12 years, and adolescent: 13–18 years.

Reference lists of identified articles were searched for additional studies using the same criteria for inclusion enumerated earlier. Finally, articles personally known to members of the committee that were not identified by other means were submitted for consideration and were included if they fulfilled the inclusion criteria.

A total of 196 articles were identified by using these search criteria. Of those, 58 were accepted as evidence for the guideline, and 138 were rejected as not meeting all requirements. A summary evidence table for the accepted articles can be found in Supplemental Information A.

Secondary Literature Search: Comorbidities of T2DM

After completion of the primary literature review, at the request of the committee, a second literature review was conducted to identify evidence relating to screening, diagnosis, and treatment of comorbidities of T2DM in children and adolescents. Similar to inclusion criteria for the primary review, an article relating to comorbidities was eligible for inclusion if it was published in 1990 or later, was written in English, and included an abstract. Again, only primary research inquiries were considered; review articles were considered if they included primary data or opinion. Children and/or adolescents in whom either T1DM or T2DM was diagnosed were required to constitute the research population; studies of adult patients were considered if $\geq 10\%$ of the population was younger than 35 years. The focus of the research article must be hyperlipidemia, microalbuminuria, retinopathy, or “comorbidities of diabetes mellitus.”

The electronic databases PubMed, Cochrane Collaboration, and Embase were searched using the following Medical Subject Headings, alone and in various combinations: diabetes,

mellitus, type 2, type 1, pediatric, T2DM, T1DM, NIDDM, hyperlipidemia, retinopathy, microalbuminuria, comorbidities, screening, RCT, meta-analysis, child, and adolescent. In addition, the Boolean operators NOT, AND, and OR were used with the aforementioned terms, also in various combinations. Search limitations included clinical trial, meta-analysis, randomized controlled trial, review, child: 6–12 years, and adolescent: 13–18 years. Reference lists of identified articles were searched for additional studies, with the use of the same criteria for inclusion enumerated earlier. Finally, articles personally known to members of the committee that were not identified by other means were submitted for consideration and were included if they fulfilled the inclusion criteria.

A total of 75 articles were identified by using these search criteria. Of those, 26 were accepted as evidence for the guideline, and 49 were rejected as not meeting all requirements. A summary evidence table for the accepted comorbidity articles can be found in Supplemental Information B.

Analysis of Available Evidence

A strict evidence-based approach was used to extract data used to develop the recommendations presented in the accompanying clinical practice guideline. Individual articles meeting the prospective search criteria were critically appraised for strength of methodology, and they were assigned an evidence level grade on the basis of guidelines published by the University of Oxford's Centre for Evidence-based Medicine, which are synthesized in the next discussion.²⁸

Levels of Evidence (Based on Methodology)

- Level 1A: Systematic review with homogeneity of included RCTs.

- Level 1B: Individual RCT with narrow CI and >80% follow-up.
- Level 2A: Systematic review with homogeneity of cohort studies.
- Level 2B: Individual cohort study, follow-up of untreated controls in an RCT, or low-quality RCT (ie, less than 80% follow-up).
- Level 2C: "Outcomes research."
- Level 3A: Systematic review with homogeneity of case-control studies.
- Level 3B: Individual case-control studies.
- Level 4: Case series; poor-quality cohort and/or case-control studies.
- Level 5: Expert opinion without explicit critical appraisal or based on physiology, bench research, or "first principles."

Grades of Evidence Supporting the Recommendations

The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines," was followed in designating grades of recommendation (Fig 1, Table 1), based on the levels of available evidence. AAP policy stipulates that the evidence in support of each key action statement be prospectively identified, appraised, and summarized and that an explicit link between level of evidence and grade of recommendation be defined.

Possible grades of recommendations range from A to D, with A being the highest. Some qualification of the grade is further allowed on the basis of subtle characteristics of the level of supporting evidence. The AAP policy statement is consistent with the grading recommendations advanced by the University of Oxford's Centre for Evidence-based Medicine. The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines" offers further details.²⁹

- Grade A: Consistent level 1 studies. (Examples include meta-analyses

with appropriate adjustments for heterogeneity, well-designed RCTs, or high-quality diagnostic studies on relevant populations.)

- Grade B: Consistent level 2 or level 3 studies or extrapolations from level 1 studies. (Examples include RCTs or diagnostic studies with methodologic flaws or performed in less relevant populations; consistent and persuasive evidence from well-designed observational trials.)
- Grade C: Level 4 studies or extrapolations from level 2 or level 3 studies. (Examples include poor-quality observational studies, including case-control and cohort design methodologies, as well as case series.)
- Grade D: Level 5 evidence, or troublingly inconsistent or inconclusive studies of any level. (Examples include case reports, expert opinion,

reasoning from first principles, or methodologically troubling studies with questionable validity.)

- Level X: Not an explicit level of evidence as outlined by the Centre for Evidence-based Medicine. Reserved for interventions that are unethical or impossible to test in a controlled or scientific fashion, in which the preponderance of benefit or harm is overwhelming, precluding rigorous investigation.

The relationship between grades of evidence supporting recommendations and recommended key action statements is depicted in Fig 1. Note that any given recommended key action statement may only be as strong as its supporting evidence will allow.

Recommended Key Action Statements

After considering the available levels of evidence and grades of recommendations, the committee formulated

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies in relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation Recommendation	

FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation.

TABLE 1 Grades of Study According to Subdivision

Evidence Quality	Medical Treatment	Nonmedical Treatment	Provider Behaviors	Social Issues
A	4	1	0	0
B	0	1	0	0
C	4	3	7	6
D	24	4	1	3

several recommended key action statements, published in the companion clinical practice guideline. As discussed previously, recommended key action statements vary in strength on the basis of the quality of the supporting evidence.

- **Strong recommendation:** The highest level of recommendation, this category is reserved for recommendations supported by grade A or grade B evidence demonstrating a preponderance of benefit or harm. Interventions based on level X evidence may also be categorized as strong on the basis of their risk/benefit profile. A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. The implication for clinicians is that they should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
- **Recommendation:** A recommended key action statement is made when the anticipated benefit exceeds the harms but the evidence is not as methodologically sound. Recommended key action statements must be supported by grade B or grade C evidence; level X evidence may also result in a recommendation depending on risk/benefit considerations. A recommendation in favor of a particular action is made when the anticipated benefits exceed

the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms. The implication for clinicians is that they would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.

- **Option:** Option statements are offered when the available evidence is grade D or the anticipated benefit is balanced with the potential harm. Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another. The implication for clinicians is that they should consider the option in their decision-making, and patient preference may have a substantial role.
- **No recommendation:** When published evidence is lacking, and/or what little evidence is available demonstrates an equivocal risk/benefit profile, no recommended key action can be offered. No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear. The implication for clinicians is that they should be alert to new published evidence that clarifies the balance of benefit versus harm.

Implementation Strategy

Implementing the guideline's recommendations to improve care processes involves identifying potential barriers to the use of the knowledge, creating strategies to address those barriers, and selecting appropriate quality improvement methods (eg,

education, audit and feedback, computer-based decision support).

Computer-mediated decision support offers an implementation mode that has been demonstrated to be effective³⁰ and that is expected to be of increasing relevance to pediatricians with the adoption of electronic health records. To facilitate translation of the recommendations into computable statements, the guideline recommendations were transformed into declarative production rule (eg, IF-THEN) statements.³¹ The Key Action Statements are displayed as production rules in Supplemental Information C. The concepts required to describe antecedent and consequent clauses in these rules were translated into the following standardized coding systems: SNOMED-CT,³² RxNorm,³³ and LOINC.³⁴

In addition, the concepts described in the guideline recommendations were translated, where possible, into elements of the National Quality Forum's Quality Data Set (QDS).³⁵ The QDS provides a framework from which performance measurement data can be derived. The QDS is intended to serve as a standard set of reusable data elements that can be used to promote quality measurement. Each QDS element includes a name, a quality data type that describes part of the clinical care process, quality data type specific attributes, a standard code set name, and a code listing. The Methods for Developing the Guidelines section displays the relevant decision variables and actions as well as coding information. A QDS listing of decision variables and actions is provided in Supplemental Information D.

RESULTS

Primary Literature Search: Treatment of T2DM

Thousands of articles were retrieved and considered on the basis of the aforementioned criteria. From those,

199 abstracts were identified for possible inclusion, and 58 were retained for systematic review. Results of the literature review are presented in the following text and listed in the evidence tables in the Supplemental Information. Of the 58 articles retained for systematic review, 5 studies were classified as grade A studies, 1 as grade B, 20 as grade C, and 32 as grade D. Articles regarding the treatment of T2DM selected for inclusion were divided into 4 major subcategories on the basis of type of treatment being discussed: (1) medical treatments (32 studies); (2) nonmedical treatments (9 studies); (3) provider behaviors (8 studies); and (4) social issues (9 studies). Detailed information about these articles is presented in Supplemental Information A. A graphic depiction of the grades of study according to subdivision is given in Table 1.

Rejected Articles

Of the 257 articles meeting search criteria, 199 were rejected, categorized as follows:

- Comorbidities: 69 studies. (Note: these articles were rejected within the context of the primary search string relating to treatment of T2DM. A second prospective literature search was conducted solely addressing comorbidities, the results of which are presented in the next section.)
- Medical treatment: 99 articles.
- Nonmedical treatment: 16 articles.
- Social issues: 12 articles.
- Provider behaviors: 3 articles.

To view the recommendations related to management of T2DM, please see the accompanying clinical practice guideline.³⁶

Secondary Literature Search: Comorbidities of T2DM

Evidence is sparse in children and adolescents regarding the risks for

developing various comorbidities of diabetes that are well recognized in adult patients. Numerous reports have documented the occurrence of comorbidities in adolescents with T2DM, but no randomized clinical trials have examined the progression and treatment of comorbidities in youth with T2DM.²⁹ The evidence that does exist is contradictory with regard to both screening and treatment recommendations. After applying the previously described search criteria and screening to thousands of articles, an additional 336 abstracts relating to comorbidities were identified for possible inclusion, of which 26 were retained for systematic review. Results of this subsequent literature review are presented in Supplemental Information E.

Articles discussing comorbidities ran the gamut of study focus, type, level of evidence, and grade of recommendation. The 26 articles that met the revised objective criteria had the following characteristics:

- Expert opinion global recommendations not based on evidence (5 articles).
- Cohort studies reporting natural history of disease and comorbidities (5 articles).
- Specific attention to comorbidity patterns in specific ethnic groups (case-control, cohort, and clinical report by using adult literature: 3 articles).
- Association between microalbuminuria and retinopathy (2 case-control, 1 cohort: 3 articles).
- Prevalence of nephropathy (cohort: 3 articles).
- Hyperlipidemia (American Heart Association [AHA] position statement on cardiovascular risks, ADA consensus statement, case series: 3 articles).
- Retinopathy (1 case-control, 1 position statement: 2 articles).

- Peripheral vascular disease (case series: 1 article).
- Systematic review of literature regarding comorbidities of T2DM in adolescents (1 article).

A graphic depiction of the grades of recommendation is given in Table 2.

Rejected Articles

A total of 310 articles did not meet primary inclusion criteria and were rejected; details are presented in Supplemental Information F. Profiles of the rejected articles are:

- Articles relating to T1DM (125 articles); specifically on the following topics:
 - Retinopathy (42 articles).
 - Vascular complications (34 articles).
 - Nephropathy (29 articles).
 - Natural history and epidemiology of T1DM (8 articles).
 - Hyperlipidemia (5 articles).
 - Risk factors for comorbidities (ie, ethnicity, puberty: 4 articles).
 - Neuropathy (3 articles).
- Articles involving adults, practice management issues, and other nonpertinent topics (118 articles).
- Articles about nondiabetic subjects, prediabetic subjects, or adults, including recommendations for testing for conditions such as hyperlipidemias and CVD (36 articles).
- Reviews, published trials, guidelines, and position statements not meeting criteria (19 articles).
- Studies addressing methods of testing for comorbidities (12 articles).

The initial search strategy for comorbidities included patients diagnosed with T1DM. The committee thus assumed that (with the exception of initiating screening) the pattern of comorbidities—and the need to screen for and treat them—would be similar between T1DM and T2DM. It was also

assumed that comorbidities would be similar between pediatric and adult patients, with length and severity of disease the driving factors. During the search, articles addressing the following themes were identified and reviewed:

- The pattern of comorbidities in T1DM versus T2DM and the role of puberty (9 articles).
- Differences in comorbidity patterns in children with T2DM compared with adults (8 articles).

Although not included in the final list of studies, these articles are included in the Supplemental Information because they resulted in an alteration to the original inclusion criteria. The results of these articles indicate that the pattern of comorbidities in children and adolescents with T2DM may not resemble that of either T1DM patients (possibly because of the influence of puberty) or adults, as was hypothesized by the committee when identifying the primary search parameters. Accordingly, the search string was modified to include only children and adolescents with the diagnosis of T2DM.

Recommendations Regarding Comorbidities

Unlike T2DM in adult patients, data are scarce in children and adolescents regarding the diagnosis, natural history, progression, screening recommendations, and treatment recommendations. Numerous reports have documented the occurrence of comorbidities in adolescents with T2DM, but no RCTs have examined the progression and treatment of comorbidities in youth with T2DM.

TABLE 2 Grades of Recommendation

Evidence Quality	No. of Studies
A	0
B	10
C	6
D	10

The available literature is conflicting regarding whether clinical signs of pathology in adults are variants of normal for adolescents, the role of puberty in diagnosis and progression of various comorbidities, the screening tests that should be performed and how they should be interpreted, when screenings should be initiated, how often screening should be performed and by whom, and how abnormal results should be treated. Medications commonly prescribed in adult patients have not been rigorously tested in children or adolescents for safety or efficacy. The peculiarities of the developing adolescent brain, typical lifestyle, and social issues confound issues of treatment effectiveness.

Despite the limited evidence available, the committee provides information on expert recommendations for the following selected comorbidities: hypertension, dyslipidemia, retinopathy, microalbuminuria, and depression. These therapeutic recommendations were summarized from expert guideline documents and are presented in detail in the following sections. The references are provided, but the committee did not independently assess the supporting evidence. Sample screening tools are provided in the Supplemental Information (see Supplemental Information H and I).

Hypertension

Hypertension is a significant comorbidity associated with endothelial dysfunction, vessel stiffness, and increased risk of future CVD and chronic kidney disease for the child with diabetes.^{37,38} It is present in 36% of youth with T2DM within 1.3 years of diagnosis³⁹ and was present in 65% of youth with T2DM enrolled in the SEARCH for Diabetes in Youth Study (SEARCH study).⁴⁰ Because development of CVD is associated with hypertension, recognition and treatment of this comorbidity are essential, especially in youth with T2DM.

Unfortunately, health care providers underdiagnose hypertension in children and adolescents (both with and without diabetes), resulting in a lack of appropriate treatment.⁴¹

Screening:

- Blood pressure should be measured with an appropriate-sized cuff and reliable equipment, monitored at every clinic visit, and plotted against norms for age, gender, and height provided in tables available at the following Web site: http://www.nhlbi.nih.gov/guidelines/hypertension/child_tbl.htm⁴² or in “The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents.”⁴³ (See the Supplemental Information for the National Institutes of Health table.)

Treatment:

- Once a diagnosis of hypertension is established, the clinician can institute appropriate treatment, which might include lifestyle change and/or pharmacologic agents. Although a complete discussion of this topic is beyond the scope of these guidelines, rational treatment guidelines exist.^{43,44} In adult patients with T2DM, concomitant treatment of hypertension has been shown to improve microvascular and macrovascular outcomes at least as much as control of BG concentrations.^{45,46} Therefore, it is the consensus of this committee that similar benefits are likely with early recognition and treatment of hypertension in the child or adolescent with increased CVD risk secondary to T2DM.^{47,48} The committee recommends appropriate surveillance and therapy as outlined in “The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents.”⁴³

- Initial treatment of blood pressure consistently at, or above, the 95th percentile on at least 3 occasions should consist of efforts at weight loss reduction, limitation of dietary salt, and increased activity.
- If, after 6 months, blood pressure is still above the 95th percentile for age, gender, and height, initiation of an angiotensin-converting enzyme (ACE) inhibitor should be considered to achieve blood pressure values that are less than the 90th percentile.
- If ACE inhibitors are not tolerated because of adverse effects (most commonly cough), an angiotensin receptor blocker should be used.
- If adequate control of hypertension is not achieved, referral to a physician specialist trained in the treatment of hypertension in youth is recommended.

Dyslipidemia

Long-term complications of T2DM in children and adolescents are not as well documented as those found in adults. It should be noted that the pediatric experience with niacin and fibrates is limited. In a review, however, Pinhas-Hamiel and Zeitler⁴⁹ noted the presence of dyslipidemia in a substantial proportion of young patients with T2DM in various populations worldwide. The SEARCH study found that 60% to 65% of 2096 youth with T2DM had hypertriglyceridemia, and 73% had a low high-density lipoprotein cholesterol level.⁵⁰ Thus, although variations exist in the criteria used for defining hyperlipidemia, there is unequivocal evidence that screening for dyslipidemia is imperative in pediatric patients with T2DM.^{49,51,52} Hyperglycemia and insulin resistance may play a direct role in dyslipidemia, and cardiovascular risk is further enhanced by the presence of other risk factors, including obesity and a family

history of early CVD.^{49,53} The AHA classifies T2DM as a tier 2 condition (moderate risk) in which accelerated atherosclerosis has been documented in patients younger than 30 years.⁵¹ The presence of 2 other risk factors, including obesity, smoking, family history of CVD, and poor exercise history, can accelerate this status to tier 1 (high risk), which is relevant to many young patients with T2DM.

Screening:

- On the basis of current recommendations by the ADA and the AHA, at the initial evaluation, all patients with T2DM should have baseline lipid screening (after initial glycemic control has been established) consisting of a complete fasting lipid profile, with follow-up testing based on the findings or every 2 years thereafter, if initial results are normal.^{51–53} (See the Supplemental Information for screening tools.)

Treatment:

The committee suggests following the AHA position statement, “Cardiovascular Risk Reduction in High-risk Pediatric Patients,” for management of dyslipidemia.⁵¹ This position statement recommends:

- Evaluation and dietary education by a registered dietitian for all patients, with initiation of intensive therapy and follow-up for patients with a BMI >95th percentile.
- Lipid targets:
 - LDL-C: Initial concentration ≥ 130 mg/dL: nutritionist training with diet <30% calories from fat, <7% calories from saturated fat, cholesterol intake <200 mg/day, and avoidance of trans fats. LDL measurements should be repeated after 6 months. If concentrations are still 130 to 160 mg/dL, statin therapy should be initiated,

with a goal of <130 mg/dL and an ideal target of <100 mg/dL.

- Triglycerides: If initial concentrations are between 150 and 600 mg/dL, patients should decrease intake of simple carbohydrates and fat, with weight loss management for those who are overweight. If levels are >700 to 1000 mg/dL at initial or follow-up visit, fibrate or niacin should be considered if the patient is older than 10 years because of increased risk of pancreatitis at these concentrations.
- Control of hypertension, per guidelines referenced previously.
- Intensification of management of hyperglycemia.
- Assessment of parental smoking history and patient smoking history if the patient is older than 10 years; active antismoking counseling at every visit and referral to a smoking cessation program, if required.
- Assessment of family history of early CVD along with current family lifestyle habits; a positive family history increases the level of risk.
- Promotion of physical exercise and limitation of sedentary activities.

Retinopathy

The eye has been called a unique window into the neural and vascular health in patients with diabetes.⁵⁴ Retinopathy is well documented in adults, both alone and in association with other comorbidities,⁵⁵ but descriptions of its frequency and associations with other comorbidities in youth are limited. Some observational and case-control studies show that retinopathy in adolescents with T2DM is present earlier than in adults, whereas others indicate that it appears much later.^{56–60}

The review by Pinhas-Hamiel and Zeitler⁴⁹ of complications of T2DM among

adolescents cited studies in which the diagnosis of retinopathy appeared to occur strikingly early in the disease process. Two large studies in the Japanese population documented early development of retinopathy in young adults, some even before the diagnosis of diabetes mellitus. In a study of 1065 patients diagnosed with T2DM before 30 years of age, Okudaira et al⁵⁷ reported the presence of retinopathy in 99 patients (9.3%) before the first visit. One hundred thirty-five patients (12.7%) developed proliferative retinopathy before 35 years of age, and 32 (23.7%) of these patients were blind by a mean age of 32 years. Bronson-Castain et al⁵⁴ used sophisticated techniques to evaluate the neural and vascular health of the retina and reported a much higher incidence of focal retinal neuropathy, retinal thinning, and retinal venular dilation in a cohort of 15 adolescent patients with T2DM matched with 26 controls. Okudaira et al observed the development of retinopathy in 394 patients diagnosed with T2DM before 30 years of age. Of the 322 patients who were free of retinopathy at entry, 88 developed background diabetic retinopathy over 5.7 years, an incidence of 57.7 per 1000 person-years. Fifty of the 160 patients with background retinopathy developed proliferative retinopathy over 7.1 years, an incidence of 17.9 per 1000 person-years. Poor glycemic control, duration of disease, and high blood pressure seemed to be the primary risk factors.

Conversely, the study by Krakoff et al⁵⁸ of 178 youth that used the proportional hazards model showed a lower risk for retinopathy in Pima Indians (compared with the Japanese study cited previously), even after adjusting for glucose concentrations and blood pressure. Similar results were reported by Farah et al⁵⁹ in 40 African American and Hispanic youth and by Karabouta et al⁶⁰ in 7 adolescent patients. It is

unclear whether these differences in results arise from variations in study design, population demographic characteristics, and/or techniques used in diagnosis. Given the variability in the results of epidemiologic studies and absence of long-term data, the committee considers it prudent for providers to follow the ADA “Standards of Medical Care in Diabetes” for identification and management of retinopathy in adolescents with T2DM, as follows⁶¹:

Screening:

- Patients with T2DM should have an initial dilated and comprehensive eye examination performed by an ophthalmologist or optometrist shortly after diabetes diagnosis.
- Subsequent examinations by an ophthalmologist should be repeated annually. Less frequent examinations may be considered (eg, every 2–3 years) after 1 or more normal eye examinations. More frequent examinations are required if retinopathy is progressing.

Treatment:

- Providers should promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy, or any proliferative diabetic retinopathy to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy.
- Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk proliferative diabetic retinopathy, clinically significant macular edema, and some cases of severe nonproliferative diabetic retinopathy.

Microalbuminuria

Microalbuminuria is a marker of vascular inflammation and a sign of

early nephropathy; it has been found to be associated with CVD risk in adults. It may be present at diagnosis in youth with T2DM.⁴⁹ Higher rates of microalbuminuria have been reported among youth with T2DM than in their peers with T1DM.^{39,59} Diabetic nephropathy may also be more frequent and severe among youth with T2DM.^{62,63} According to the ADA statement “Care of Children and Adolescents with Type 1 Diabetes,” the definition of microalbuminuria is either:

- “Albumin-to-creatinine ratio 30–299 mg/g in a spot urine sample; slightly higher values can be used in females because of the difference in creatinine excretion,”^{7,64} or
- “Timed overnight or 24-hour collections: albumin excretion rate of 20–199 mcg/min.”⁷

According to the ADA, “an abnormal value should be repeated as exercise, smoking, and menstruation can affect results and albumin excretion can vary from day to day. The diagnosis of persistent abnormal microalbumin excretion requires documentation of two of three consecutive abnormal values obtained on different days.”^{7,65} In addition, nondiabetes-related causes of renal disease should be excluded; consultation with specialists trained in the care of children with renal diseases should be considered as required. It should be noted that orthostatic proteinuria is not uncommon in adolescents and usually is considered benign. For that reason, all patients with documented microalbuminuria should have a first morning void immediately on arising to determine if this is the case. Orthostatic proteinuria does not require treatment with medication.

The committee considers it prudent for providers to follow the ADA “Standards of Medical Care in Diabetes” for the identification and management of

microalbuminuria in adolescents with T2DM, as described here. Note that monitoring should always be done on a first morning void specimen:

Screening:

- Screening for microalbuminuria should begin at the time of T2DM diagnosis and be repeated annually.
- An annual random spot urine sample for microalbumin-to-creatinine ratio is recommended.⁶⁶

Treatment:

- Treatment with an ACE inhibitor should be initiated in nonpregnant individuals with confirmed persistent microalbuminuria from 2 additional urine specimens, even if blood pressure is not elevated.
- If possible, treatment with an ACE inhibitor should be titrated to normalization of microalbumin excretion. "Microalbumin excretion should be monitored at three- to six-month intervals to assess both the patient's response to therapy and the disease progression, and therapy should be titrated to achieve as normal an albumin-to-creatinine ratio as possible."⁷

Additional relevant issues noted in the ADA statement "Care of Children and Adolescents with Type 1 Diabetes" include⁷:

- Concomitant hypertension should be addressed. If present, hypertension should be aggressively treated to achieve normotension for age, sex, and height.
- Patients should be educated about the importance of attention to glycemic control and avoidance or cessation of smoking in preventing and/or reversing diabetic nephropathy.
- If medical treatment is unsatisfactory, referral to a nephrologist should be considered.

Depression

Depression is a significant comorbidity that can complicate the medical management of diabetes and is associated with poor adherence. Longitudinal studies of the association between T2DM and depression among youth are not available. In a longitudinal study among youth with T1DM, however, Kovacs et al⁶⁷ estimated the rate of psychiatric disorders to be 3 times higher in youth with diabetes than in those without diabetes, with the increased morbidity primarily attributable to major depression.^{7,67,68} In addition, cross-sectional data from the SEARCH study have shown the prevalence of depressed mood to be higher among males with T2DM than among males with T1DM.⁶⁷ Lawrence et al⁶⁸ also found higher levels of depressed mood to be associated with poor glycemic control and number of emergency department visits among participants with both T1DM and T2DM, compared with youth with T1DM and T2DM who had "minimal" levels of depressed mood.

Because depression is associated with poor adherence to diabetic treatment recommendations, its identification and proper management are essential for maximizing therapeutic success. Given the serious nature of this comorbidity and its propensity for poor metabolic control, the committee recommends that clinicians assess youth with T2DM for depression at diagnosis; perform periodic, routine screening for depression on all youth with T2DM, especially those with frequent emergency department visits or poor glycemic control; and promptly refer youth who have positive screenings to appropriate mental health care providers for treatment. Addressing a family history of diabetes and its effect on the family unit can be a major factor in depression as well as compliance with the disease management needs.

Screening:

- According to the American Psychiatric Association, a diagnosis of major depressive disorder requires⁶⁹:
 - (a). The presence of 5 or more of the following symptoms within the same 2-week period and represents a change from previous functioning. At least 1 of the symptoms is either depressed mood or loss of interest or pleasure.
- Depressed mood most of the day, nearly every day, as indicated by either substantive report or observation made by others. (Note that in children and adolescents, this can be irritable mood.)
- Markedly diminished interest or pleasure in all, or nearly all, activities most of the day, nearly every day.
- Significant weight loss when not dieting or weight gain (eg, more than 5% of body weight in a month), or increased or decreased appetite nearly every day. (Note that in children and adolescents, this should include failure to make expected weight gains.)
- Insomnia or hypersomnia nearly every day.
- Psychomotor agitation or retardation nearly every day (observable by others, not merely the subject's feeling restless or slowed down).
- Fatigue or loss of energy nearly every day.
- Feelings of worthlessness or inappropriate guilt (which may be delusional) nearly every day.
- Diminished ability to think or to concentrate, or indecisiveness, nearly every day.
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt, or a specific plan to commit suicide.

- (b). The symptoms do not meet the criteria for a mixed episode (defined as a specific time period in which the individual experiences nearly daily fluctuations in mood that qualify for diagnoses of manic episode and major depressive episode).
 - (c). The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
 - (d). The symptoms are not due to the direct physiologic effects of a substance (eg, a drug of abuse, medication) or a general medical condition (eg, hypothyroidism).
 - (e). The symptoms are not better accounted for by bereavement (ie, after the loss of a loved one), symptoms persist longer than 2 months, or symptoms are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.
 - Another potentially valuable screening tool for depression is the Center for Epidemiologic Studies Depression Scale (CES-D), a 20-item scale originally developed for use in adults⁷⁰ but which has been used subsequently in studies of youth as young as 12 years.^{71–74} (See Supplemental Information G for this scale.)
- with other obesity-related medical conditions, many of which, when discovered, necessitate consultation with specialists who have specific expertise in the field. These associated conditions include:
- Nonalcoholic fatty liver disease: Baseline aspartate aminotransferase and alanine aminotransferase concentrations should be obtained, especially if treatment with lipid-lowering drugs is instituted. Referral to a pediatric or internal medicine gastroenterologist may be indicated.
 - Obstructive sleep apnea: The diagnosis of obstructive sleep apnea can only be made reliably by using a sleep study. If the diagnosis is made, an electrocardiogram and possibly an echocardiogram should be obtained to rule out right ventricular hypertrophy. Referral to a pediatric cardiologist, internal medicine cardiologist, or sleep specialist may be indicated.
 - Orthopedic problems: These comorbidities (especially slipped capital femoral epiphysis and Blount disease) require immediate referral to a specialist in orthopedics and will limit the physical activity that can be prescribed to the individual.

COMPLEMENTARY AND ALTERNATIVE MEDICINE

The clinical practice guidelines do not present any evidence-based recommendations for the use of complementary and alternative medicine (CAM) to treat T2DM in children and adolescents. Limited data are available on CAM, and none is specific to this age group. However, noting that adult patients with diabetes are 1.6 times more likely to use CAM than are individuals without diabetes, the committee believes it is important for clinicians to encourage their patients to communicate openly about the use

of CAM (especially because the parents may have diabetes themselves) and, when acknowledged, to differentiate between coadministration with the prescribed therapy versus replacement of (and, thus, noncompliance with) the prescribed therapy.⁷⁵

CAM is most likely to be used by West Indian, African, Indian, Latin American, and Asian subjects.⁷⁶ CAM is also more common in families with higher income and education levels and an increased interest in self-care. One multicenter study conducted in Germany found that, among 228 families with a T1DM diagnosis, 18.4% reported using at least 1 form of CAM.⁷⁷ Reported parental motivators for using CAM for their children included the hope of improving their well-being (92.1%); the desire to try every available treatment option (77.8%); and the assumption that CAM has fewer adverse effects than conventional therapy (55.2%). Many forms of CAM are used because of patient-perceived inadequacies of current treatments.⁷⁵

A wide variety of CAM dietary supplements are targeted at patients with diabetes and promise to lower BG concentrations or prevent and/or treat complications associated with the disease. Common supplements used by individuals with diabetes include aloe, bitter melon, chromium, cinnamon, fenugreek, ginseng, gymnema, and nopal.⁷⁸ These products lack product standardization and are not regulated by the US Food and Drug Administration for either safety or possible complications. Although these supplements may or may not have proven beneficial effects on diabetes, many might have harmful adverse effects and/or lead to medication interactions. Adverse effects from dietary supplements can include gastrointestinal discomfort, hypoglycemia, favism, insomnia, and increased blood pressure.⁷⁸

Treatment:

- Recognition of depression should trigger a referral to a mental health care provider skilled in addressing this condition in children and adolescents.

Other Comorbidities or Associated Medical Conditions

In addition to the comorbidities mentioned previously, T2DM is associated

In addition to dietary supplements, patients may use forms of CAM that include prayer, acupuncture, massage, hot tub therapy, biofeedback, and yoga. The University of Chicago's Division of Pediatric Endocrinology interviewed 106 families with T1DM and found that 33% of children had tried CAM in the past year; the most common form used was faith-healing or prayer.⁷⁹ Parents who reported the use of CAM for their children were also more likely to report having experienced struggles with adherence to conventional medicine.

It is the committee's opinion that providers should question patients on their use of CAM and also educate patients on potential adverse effects, review evidence for efficacy, and discourage the use of potentially dangerous or ineffective products.

SUMMARY

The clinical practice guideline that this technical report accompanies provides evidence-based recommendations on the management of patients between 10 and 18 years of age who have been diagnosed with T2DM. The document does not pertain to patients with impaired glucose tolerance, isolated insulin resistance, or prediabetes, nor does it pertain to obese but nondiabetic youth. It emphasizes the use of management modalities that have been

shown to affect clinical outcomes in this pediatric population. The clinical practice guideline addresses situations in which either insulin or metformin is the preferred first-line treatment of children and adolescents with T2DM. It suggests integrating lifestyle modifications (ie, diet and exercise) in concert with medication rather than as an isolated initial treatment approach. Guidelines for frequency of monitoring HbA1c and finger-stick BG concentrations are presented. The clinical practice guideline is intended to assist clinician decision-making rather than replace clinical judgment and/or establish a protocol for the care of all children with this condition. These recommendations may not provide the only appropriate approach to the management of children with T2DM. Providers should consult experts trained in the care of children and adolescents with T2DM when treatment goals are not met or when therapy with insulin is initiated.

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SUBCOMMITTEE ON TYPE 2 DIABETES (OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2008–2012)

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ERRATUM

An error occurred in the American Academy of Pediatrics “Technical Report: Management of Type 2 Diabetes Mellitus in Children and Adolescents” published in the February 2013 issue of *Pediatrics* (2013;131[2]:e648–e664).

On page e651, third column, under “Definitions,” the first sentence should read as follows: “Children and adolescents: children <10 years of age; adolescents ≥10 years but ≤18 years of age.”

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Diabetes Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
— Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Type 2 Diabetes Mellitus
- AAP Patient Education Handout
— *Type 2 Diabetes: Tips for Healthy Living*

Action Statement Summary

Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

Key Action Statement 1

Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between T1DM and T2DM is unclear; and, in usual cases, should initiate insulin therapy for patients:

- who have random venous or plasma BG concentrations ≥ 250 mg/dL; or
- whose HbA1c is $>9\%$.

(Strong Recommendation: evidence quality X, validating studies cannot be performed, and C, observational studies and expert opinion; preponderance of benefit over harm.)

Key Action Statement 2

In all other instances, clinicians should initiate a lifestyle modification program, including nutrition and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM. (Strong recommendation: evidence quality B; 1 RCT showing improved outcomes with metformin versus lifestyle; preponderance of benefits over harms.)

Key Action Statement 3

The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for BG and HbA1c concentrations are not being met. (Option: evidence quality D; expert opinion and studies in children with T1DM and in adults with T2DM; preponderance of benefits over harms.)

Key Action Statement 4

The committee suggests that clinicians advise patients to monitor finger-stick BG concentrations in those who are taking insulin or other medications with a risk of hypoglycemia; or

- are initiating or changing their diabetes treatment regimen; or
- have not met treatment goals; or
- have intercurrent illnesses.

(Option: evidence quality D; expert consensus. Preponderance of benefits over harms.)

Key Action Statement 5

The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in the nutrition counseling of patients with T2DM both at the time of diagnosis and as part of ongoing management. (Option: evidence quality D; expert opinion; preponderance of benefits over harms. Role of patient preference is dominant.)

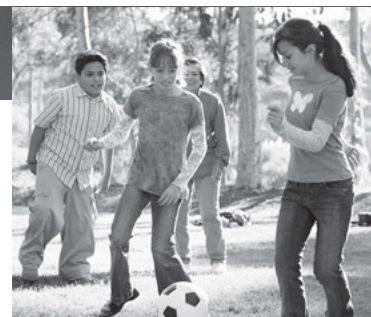
Key Action Statement 6

The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic screen time to less than 2 hours per day. (Option: evidence quality D; expert opinion and evidence from studies of metabolic syndrome and obesity; preponderance of benefits over harms. Role of patient preference is dominant.)

Coding Quick Reference for Type 2 Diabetes Mellitus

ICD-9-CM	ICD-10-CM
250.00 Type 2 diabetes mellitus, controlled	E11.8 Type 2 diabetes mellitus with unspecified complications E11.9 Type 2 diabetes mellitus without complications E11.649 Type 2 diabetes mellitus with hypoglycemia without coma E11.65 Type 2 diabetes mellitus with hyperglycemia E13.9 Other specified diabetes mellitus without complications
250.02 Type 2 diabetes mellitus, uncontrolled	Use codes above (E11.8–E13.9). ICD-10-CM does not discern between controlled and uncontrolled.

Type 2 Diabetes: Tips for Healthy Living



Children with type 2 diabetes can live a healthy life. If your child has been diagnosed with type 2 diabetes, your child's doctor will talk with you about the importance of lifestyle and medication in keeping your child's blood glucose (blood sugar) levels under control.

Read on for information from the American Academy of Pediatrics (AAP) about managing blood glucose and creating plans for healthy living.

What is blood glucose?

Glucose is found in the blood and is the body's main source of energy. The food your child eats is broken down by the body into glucose. Glucose is a type of sugar that gives energy to the cells in the body.

The cells need the help of insulin to take the glucose from the blood to the cells. Insulin is made by an organ called the pancreas.

In children with type 2 diabetes, the pancreas does not make enough insulin and the cells don't use the insulin very well.

Why is it important to manage blood glucose levels?

Glucose will build up in the blood if it cannot be used by the cells. High blood glucose levels can damage many parts of the body, such as the eyes, kidneys, nerves, and heart.

Your child's blood glucose levels may need to be checked on a regular schedule to make sure the levels do not get too high. Your child's doctor will tell you what your child's blood glucose level should be. You and your child will need to learn how to use a glucose meter. Blood glucose levels can be quickly and easily measured using a glucose meter. First, a lancet is used to prick the skin; then a drop of blood from your child's finger is placed on a test strip that is inserted into the meter.

Are there medicines for type 2 diabetes?

Insulin in a shot or another medicine by mouth may be prescribed by your child's doctor if needed to help control your child's blood glucose levels. If your child's doctor has prescribed a medicine, it's important that your child take it as directed. Side effects from certain medicines may include bloating or gassiness. Check with your child's doctor if you have questions.

Along with medicines, your child's doctor will suggest changes to your child's diet and encourage your child to be physically active.

Tips for healthy living

A healthy diet and staying active are especially important for children with type 2 diabetes. Your child's blood glucose levels are easier to manage when your child is at a healthy weight.

Create a plan for eating healthy

Talk with your child's doctor and registered dietitian about a meal plan that meets the needs of your child. The following tips can help you select foods that are healthy and contain a high content of nutrients (protein, vitamins, and minerals):

- Eat at least 5 servings of fruits and vegetables each day.
- Include high-fiber, whole-grain foods such as brown rice, whole-grain pasta, corns, peas, and breads and cereals at meals. Sweet potatoes are also a good choice.
- Choose lower-fat or fat-free toppings like grated low-fat parmesan cheese, salsa, herbed cottage cheese, nonfat/low-fat gravy, low-fat sour cream, low-fat salad dressing, or yogurt.
- Select lean meats such as skinless chicken and turkey, fish, lean beef cuts (round, sirloin, chuck, loin, lean ground beef—no more than 15% fat content), and lean pork cuts (tenderloin, chops, ham). Trim off all visible fat. Remove skin from cooked poultry before eating.
- Include healthy oils such as canola or olive oil in your diet. Choose margarine and vegetable oils without trans fats made from canola, corn, sunflower, soybean, or olive oils.
- Use nonstick vegetable sprays when cooking.
- Use fat-free cooking methods such as baking, broiling, grilling, poaching, or steaming when cooking meat, poultry, or fish.
- Serve vegetable- and broth-based soups, or use nonfat (skim) or low-fat (1%) milk or evaporated skim milk when making cream soups.
- Use the Nutrition Facts label on food packages to find foods with less saturated fat per serving. Pay attention to the serving size as you make choices. Remember that the percent daily values on food labels are based on portion sizes and calorie levels for adults.

Create a plan for physical activity

Physical activity, along with proper nutrition, promotes lifelong health. Following are some ideas on how to get fit:

- **Encourage your child to be active at least 1 hour a day.** Active play is the best exercise for younger children! Parents can join their children and have fun while being active too. School-aged child should participate every day in 1 hour or more of moderate to vigorous physical activity that is right for their age, is enjoyable, and involves a variety of activities.
- **Limit television watching and computer use.** The AAP discourages TV and other media use by children younger than 2 years and encourages interactive play. For older children, total entertainment screen time should be limited to less than 1 to 2 hours per day.
- **Keep an activity log.** The use of activity logs can help children and teens keep track of their exercise programs and physical activity. Online tools can be helpful.

- **Get the whole family involved.** It is a great way to spend time together. Also, children who regularly see their parents enjoying sports and physical activity are more likely to do so themselves.
- **Provide a safe environment.** Make sure your child's equipment and chosen site for the sport or activity are safe. Make sure your child's clothing is comfortable and appropriate.

For more information

National Diabetes Education Program

<http://ndep.nih.gov>

Listing of resources does not imply an endorsement by the American Academy of Pediatrics (AAP). The AAP is not responsible for the content of the resources mentioned in this publication. Web site addresses are as current as possible, but may change at any time.

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From your doctor

American Academy
of Pediatrics



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Early Detection of Developmental Dysplasia of the Hip

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- *Clinical Practice Guideline*
- *Technical Report Summary*

Readers of this clinical practice guideline are urged to review the technical report to enhance the evidence-based decision-making process. The full technical report is available on the companion CD-ROM.

AMERICAN ACADEMY OF PEDIATRICS

Committee on Quality Improvement, Subcommittee on Developmental Dysplasia of the Hip

Clinical Practice Guideline: Early Detection of Developmental Dysplasia of the Hip

ABSTRACT. *Developmental dysplasia of the hip* is the preferred term to describe the condition in which the femoral head has an abnormal relationship to the acetabulum. Developmental dysplasia of the hip includes frank dislocation (luxation), partial dislocation (subluxation), instability wherein the femoral head comes in and out of the socket, and an array of radiographic abnormalities that reflect inadequate formation of the acetabulum. Because many of these findings may not be present at birth, the term *developmental* more accurately reflects the biologic features than does the term *congenital*. The disorder is uncommon. The earlier a dislocated hip is detected, the simpler and more effective is the treatment. Despite newborn screening programs, dislocated hips continue to be diagnosed later in infancy and childhood,¹⁻¹¹ in some instances delaying appropriate therapy and leading to a substantial number of malpractice claims. The objective of this guideline is to reduce the number of dislocated hips detected later in infancy and childhood. The target audience is the primary care provider. The target patient is the healthy newborn up to 18 months of age, excluding those with neuromuscular disorders, myelodysplasia, or arthrogryposis.

ABBREVIATIONS. DDH, developmental dysplasia of the hip; AVN, avascular necrosis of the hip.

BIOLOGIC FEATURES AND NATURAL HISTORY

Understanding the developmental nature of developmental dysplasia of the hip (DDH) and the subsequent spectrum of hip abnormalities requires a knowledge of the growth and development of the hip joint.¹² Embryologically, the femoral head and acetabulum develop from the same block of primitive mesenchymal cells. A cleft develops to separate them at 7 to 8 weeks' gestation. By 11 weeks' gestation, development of the hip joint is complete. At birth, the femoral head and the acetabulum are primarily cartilaginous. The acetabulum continues to develop postnatally. The growth of the fibrocartilaginous rim (the labrum) that surrounds

the bony acetabulum deepens the socket. Development of the femoral head and acetabulum are intimately related, and normal adult hip joints depend on further growth of these structures. Hip dysplasia may occur in utero, perinatally, or during infancy and childhood.

The acronym DDH includes hips that are unstable, subluxated, dislocated (luxated), and/or have malformed acetabula. A hip is *unstable* when the tight fit between the femoral head and the acetabulum is lost and the femoral head is able to move within (subluxated) or outside (dislocated) the confines of the acetabulum. A *dislocation* is a complete loss of contact of the femoral head with the acetabulum. Dislocations are divided into 2 types: teratologic and typical.¹² *Teratologic dislocations* occur early in utero and often are associated with neuromuscular disorders, such as arthrogryposis and myelodysplasia, or with various dysmorphic syndromes. The *typical dislocation* occurs in an otherwise healthy infant and may occur prenatally or postnatally.

During the immediate newborn period, laxity of the hip capsule predominates, and, if clinically significant enough, the femoral head may spontaneously dislocate and relocate. If the hip spontaneously relocates and stabilizes within a few days, subsequent hip development usually is normal. If subluxation or dislocation persists, then structural anatomic changes may develop. A deep concentric position of the femoral head in the acetabulum is necessary for normal development of the hip. When not deeply reduced (subluxated), the labrum may become everted and flattened. Because the femoral head is not reduced into the depth of the socket, the acetabulum does not grow and remodel and, therefore, becomes shallow. If the femoral head moves further out of the socket (dislocation), typically superiorly and laterally, the inferior capsule is pulled upward over the now empty socket. Muscles surrounding the hip, especially the adductors, become contracted, limiting abduction of the hip. The hip capsule constricts; once this capsular constriction narrows to less than the diameter of the femoral head, the hip can no longer be reduced by manual manipulative maneuvers, and operative reduction usually is necessary.

The hip is at risk for dislocation during 4 periods: 1) the 12th gestational week, 2) the 18th gestational week, 3) the final 4 weeks of gestation, and 4) the postnatal period. During the 12th gestational week, the hip is at risk as the fetal lower limb rotates medially. A dislocation at this time is termed teratologic. All elements of the hip joint develop abnor-

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

The Practice Guideline, "Early Detection of Developmental Dysplasia of the Hip," was reviewed by appropriate committees and sections of the American Academy of Pediatrics (AAP) including the Chapter Review Group, a focus group of office-based pediatricians representing each AAP District: Gene R. Adams, MD; Robert M. Corwin, MD; Diane Fuquay, MD; Barbara M. Harley, MD; Thomas J. Herr, MD, Chair; Kenneth E. Matthews, MD; Robert D. Mines, MD; Lawrence C. Pakula, MD; Howard B. Weinblatt, MD; and Delosa A. Young, MD. The Practice Guideline was also reviewed by relevant outside medical organizations as part of the peer review process. PEDIATRICS (ISSN 0031 4005). Copyright © 2000 by the American Academy of Pediatrics.

mally. The hip muscles develop around the 18th gestational week. Neuromuscular problems at this time, such as myelodysplasia and arthrogryposis, also lead to teratologic dislocations. During the final 4 weeks of pregnancy, mechanical forces have a role. Conditions such as oligohydramnios or breech position predispose to DDH.¹³ Breech position occurs in ~3% of births, and DDH occurs more frequently in breech presentations, reportedly in as many as 23%. The frank breech position of hip flexion and knee extension places a newborn or infant at the highest risk. Postnatally, infant positioning such as swaddling, combined with ligamentous laxity, also has a role.

The true incidence of dislocation of the hip can only be presumed. There is no “gold standard” for diagnosis during the newborn period. Physical examination, plane radiography, and ultrasonography all are fraught with false-positive and false-negative results. Arthrography (insertion of contrast medium into the hip joint) and magnetic resonance imaging, although accurate for determining the precise hip anatomy, are inappropriate methods for screening the newborn and infant.

The reported incidence of DDH is influenced by genetic and racial factors, diagnostic criteria, the experience and training of the examiner, and the age of the child at the time of the examination. Wynne-Davies¹⁴ reported an increased risk to subsequent children in the presence of a diagnosed dislocation (6% risk with healthy parents and an affected child, 12% risk with an affected parent, and 36% risk with an affected parent and 1 affected child). DDH is not always detectable at birth, but some newborn screening surveys suggest an incidence as high as 1 in 100 newborns with evidence of instability, and 1 to 1.5 cases of dislocation per 1000 newborns. The incidence of DDH is higher in girls. Girls are especially susceptible to the maternal hormone relaxin, which may contribute to ligamentous laxity with the resultant instability of the hip. The left hip is involved 3 times as commonly as the right hip, perhaps related to the left occiput anterior positioning of most non-breech newborns. In this position, the left hip resides posteriorly against the mother’s spine, potentially limiting abduction.

PHYSICAL EXAMINATION

DDH is an evolving process, and its physical findings on clinical examination change.^{12,15,16} The newborn must be relaxed and preferably examined on a firm surface. Considerable patience and skill are required. The physical examination changes as the child grows older. No signs are pathognomonic for a dislocated hip. The examiner must look for asymmetry. Indeed, bilateral dislocations are more difficult to diagnose than unilateral dislocations because symmetry is retained. Asymmetrical thigh or gluteal folds, better observed when the child is prone, apparent limb length discrepancy, and restricted motion, especially abduction, are significant, albeit not pathognomonic signs. With the infant supine and the pelvis stabilized, abduction to 75° and adduction to

30° should occur readily under normal circumstances.

The 2 maneuvers for assessing hip stability in the newborn are the Ortolani and Barlow tests. The Ortolani elicits the sensation of the dislocated hip reducing, and the Barlow detects the unstable hip dislocating from the acetabulum. The Ortolani is performed with the newborn supine and the examiner’s index and middle fingers placed along the greater trochanter with the thumb placed along the inner thigh. The hip is flexed to 90° but not more, and the leg is held in neutral rotation. The hip is gently abducted while lifting the leg anteriorly. With this maneuver, a “clunk” is felt as the dislocated femoral head reduces into the acetabulum. This is a positive Ortolani sign. The Barlow provocative test is performed with the newborn positioned supine and the hips flexed to 90°. The leg is then gently adducted while posteriorly directed pressure is placed on the knee. A palpable clunk or sensation of movement is felt as the femoral head exits the acetabulum posteriorly. This is a positive Barlow sign. The Ortolani and Barlow maneuvers are performed 1 hip at a time. Little force is required for the performance of either of these tests. The goal is not to prove that the hip can be dislocated. Forceful and repeated examinations can break the seal between the labrum and the femoral head. These strongly positive signs of Ortolani and Barlow are distinguished from a large array of soft or equivocal physical findings present during the newborn period. High-pitched clicks are commonly elicited with flexion and extension and are inconsequential. A dislocatable hip has a rather distinctive clunk, whereas a subluxable hip is characterized by a feeling of looseness, a sliding movement, but without the true Ortolani and Barlow clunks. Separating true dislocations (clunks) from a feeling of instability and from benign adventitious sounds (clicks) takes practice and expertise. This guideline recognizes the broad range of physical findings present in newborns and infants and the confusion of terminology generated in the literature. By 8 to 12 weeks of age, the capsule laxity decreases, muscle tightness increases, and the Barlow and Ortolani maneuvers are no longer positive regardless of the status of the femoral head. In the 3-month-old infant, limitation of abduction is the most reliable sign associated with DDH. Other features that arouse suspicion include asymmetry of thigh folds, a positive Allis or Galeazzi sign (relative shortness of the femur with the hips and knees flexed), and discrepancy of leg lengths. These physical findings alert the examiner that abnormal relationships of the femoral head to the acetabulum (dislocation and subluxation) *may* be present.

Maldevelopments of the acetabulum alone (acetabular dysplasia) can be determined only by imaging techniques. Abnormal physical findings may be absent in an infant with acetabular dysplasia but no subluxation or dislocation. Indeed, because of the confusion, inconsistencies, and misuse of language in the literature (eg, an Ortolani sign called a click by some and a clunk by others), this guideline uses the following definitions.

- A *positive examination* result for DDH is the Barlow or Ortolani sign. This is the clunk of dislocation or reduction.
- An *equivocal examination* or *warning signs* include an array of physical findings that may be found in children with DDH, in children with another orthopaedic disorder, or in children who are completely healthy. These physical findings include asymmetric thigh or buttock creases, an apparent or true short leg, and limited abduction. These signs, used singly or in combination, serve to raise the pediatrician's index of suspicion and act as a threshold for referral. Newborn soft tissue hip clicks are not predictive of DDH¹⁷ but may be confused with the Ortolani and Barlow clunks by some screening physicians and thereby be a reason for referral.

IMAGING

Radiographs of the pelvis and hips have historically been used to assess an infant with suspected DDH. During the first few months of life when the femoral heads are composed entirely of cartilage, radiographs have limited value. Displacement and instability may be undetectable, and evaluation of acetabular development is influenced by the infant's position at the time the radiograph is performed. By 4 to 6 months of age, radiographs become more reliable, particularly when the ossification center develops in the femoral head. Radiographs are readily available and relatively low in cost.

Real-time ultrasonography has been established as an accurate method for imaging the hip during the first few months of life.^{15,18–25} With ultrasonography, the cartilage can be visualized and the hip can be viewed while assessing the stability of the hip and the morphologic features of the acetabulum. In some clinical settings, ultrasonography can provide information comparable to arthrography (direct injection of contrast into the hip joint), without the need for sedation, invasion, contrast medium, or ionizing radiation. Although the availability of equipment for ultrasonography is widespread, accurate results in hip sonography require training and experience. Although expertise in pediatric hip ultrasonography is increasing, this examination may not always be available or obtained conveniently. Ultrasonographic techniques include *static evaluation* of the morphologic features of the hip, as popularized in Europe by Graf,²⁶ and a *dynamic evaluation*, as developed by H arcke²⁰ that assesses the hip for stability of the femoral head in the socket, as well as static anatomy. Dynamic ultrasonography yields more useful information. With both techniques, there is considerable interobserver variability, especially during the first 3 weeks of life.^{7,27}

Experience with ultrasonography has documented its ability to detect abnormal position, instability, and dysplasia not evident on clinical examination. Ultrasonography during the first 4 weeks of life often reveals the presence of minor degrees of instability and acetabular immaturity. Studies^{7,28,29} indicate that nearly all these mild early findings, which will not be apparent on physical examination, resolve spontane-

ously without treatment. Newborn screening with ultrasonography has required a high frequency of reexamination and results in a large number of hips being unnecessarily treated. One study²³ demonstrates that a screening process with higher false-positive results also yields increased prevention of late cases. Ultrasonographic screening of all infants at 4 to 6 weeks of age would be expensive, requiring considerable resources. This practice is yet to be validated by clinical trial. *Consequently, the use of ultrasonography is recommended as an adjunct to the clinical evaluation.* It is the technique of choice for clarifying a physical finding, assessing a high-risk infant, and monitoring DDH as it is observed or treated. Used in this selective capacity, it can guide treatment and may prevent overtreatment.

PRETERM INFANTS

DDH may be unrecognized in prematurely born infants. When the infant has cardiorespiratory problems, the diagnosis and management are focused on providing appropriate ventilatory and cardiovascular support, and careful examination of the hips may be deferred until a later date. The most complete examination the infant receives may occur at the time of discharge from the hospital, and this single examination may not detect subluxation or dislocation. Despite the medical urgencies surrounding the preterm infant, it is critical to examine the entire child.

METHODS FOR GUIDELINE DEVELOPMENT

Our goal was to develop a practice parameter by using a process that would be based whenever possible on available evidence. The methods used a combination of expert panel, decision modeling, and evidence synthesis³⁰ (see the Technical Report available on *Pediatrics electronic pages* at www.pediatrics.org). The predominant methods recommended for such evidence synthesis are generally of 2 types: a *data-driven* method and a *model-driven*^{31,32} method. In data-driven methods, the analyst finds the best data available and induces a conclusion from these data. A model-driven method, in contrast, begins with an effort to define the context for evidence and then searches for the data as defined by that context. Data-driven methods are useful when the quality of evidence is high. A careful review of the medical literature revealed that the published evidence about DDH did not meet the criteria for high quality. There was a paucity of randomized clinical trials.⁸ We decided, therefore, to use the model-driven method.

A decision model was constructed based on the perspective of practicing clinicians and determining the best strategy for screening and diagnosis. The target child was a full-term newborn with no obvious orthopaedic abnormalities. We focused on the various options available to the pediatrician* for the detection of DDH, including screening by physical examination, screening by ultrasonography, and episodic screening during health supervision. Because

*In this guideline, the term *p ediatrician* includes the range of pediatric primary care providers, eg, family practitioners and pediatric nurse practitioners.

the detection of a dislocated hip usually results in referral by the pediatrician, and because management of DDH is not in the purview of the pediatrician's care, treatment options are not included. We also included in our model a wide range of options for detecting DDH during the first year of life if the results of the newborn screen are negative.

The outcomes on which we focused were a dislocated hip at 1 year of age as the major morbidity of the disease and avascular necrosis of the hip (AVN) as the primary complication of DDH treatment. AVN is a loss of blood supply to the femoral head resulting in abnormal hip development, distortion of shape, and, in some instances, substantial morbidity. Ideally, a gold standard would be available to define DDH at any point in time. However, as noted, no gold standard exists except, perhaps, arthrography of the hip, which is an inappropriate standard for use in a detection model. Therefore, we defined outcomes in terms of the *process of care*. We reviewed the literature extensively. The purpose of the literature review was to provide the probabilities required by the decision model since there were no randomized clinical trials. The article or chapter title and the abstracts were reviewed by 2 members of the methodology team and members of the subcommittee. Articles not rejected were reviewed, and data were abstracted that would provide evidence for the probabilities required by the decision model. As part of the literature abstraction process, the evidence quality in each article was assessed. A computer-based literature search, hand review of recent publications, or examination of the reference section for other articles ("ancestor articles") identified 623 articles; 241 underwent detailed review, 118 of which provided some data. Of the 100 ancestor articles, only 17 yielded useful articles, suggesting that our accession process was complete. By traditional epidemiologic standards,³³ the quality of the evidence in this set of articles was uniformly low. There were few controlled trials and few studies of the follow-up of infants for whom the results of newborn examinations were negative. When the evidence was poor or lacking entirely, extensive discussions among members of the committee and the expert opinion of outside consultants were used to arrive at a consensus. No votes were taken. Disagreements were discussed, and consensus was achieved.

The available evidence was distilled in 3 ways.

First, estimates were made of DDH at birth in infants without risk factors. These estimates constituted the baseline risk. Second, estimates were made of the rates of DDH in the children with risk factors. These numbers guide clinical actions: rates that are too high might indicate referral or different follow-up despite negative physical findings. Third, each screening strategy (pediatrician-based, orthopaedist-based, and ultrasonography-based) was scored for the estimated number of children given a diagnosis of DDH at birth, at mid-term (4–12 months of age), and at late-term (12 months of age and older) and for the estimated number of cases of AVN incurred, assuming that all children given a diagnosis of DDH would be treated. These numbers suggest the best strategy, balancing DDH detection with incurring adverse effects.

The baseline estimate of DDH based on orthopaedic screening was 11.5/1000 infants. Estimates from pediatric screening were 8.6/1000 and from ultrasonography were 25/1000. The 11.5/1000 rate translates into a rate for not-at-risk boys of 4.1/1000 boys and a rate for not-at-risk girls of 19/1000 girls. These numbers derive from the facts that the relative risk—the rate in girls divided by the rate in boys across several studies—is 4.6 and because infants are split evenly between boys and girls, so $.5 \times 4.1/1000 + .5 \times 19/1000 = 11.5/1000$.^{34,35} We used these baseline rates for calculating the rates in other risk groups. Because the relative risk of DDH for children with a positive family history (first-degree relatives) is 1.7, the rate for boys with a positive family history is $1.7 \times 4.1 = 6.4/1000$ boys, and for girls with a positive family history, $1.7 \times 19 = 32/1000$ girls. Finally, the relative risk of DDH for breech presentation (of all kinds) is 6.3, so the risk for breech boys is $7.0 \times 4.1 = 29/1000$ boys and for breech girls, $7.0 \times 19 = 133/1000$ girls. These numbers are summarized in Table 1.

These numbers suggest that boys without risk or those with a family history have the lowest risk; girls without risk and boys born in a breech presentation have an intermediate risk; and girls with a positive family history, and especially girls born in a breech presentation, have the highest risks. Guidelines, considering the risk factors, should follow these risk profiles. Reports of newborn screening for DDH have included various screening techniques. In some, the screening clinician was an orthopaedist, in

TABLE 1. Relative and Absolute Risks for Finding a Positive Examination Result at Newborn Screening by Using the Ortolani and Barlow Signs

Newborn Characteristics	Relative Risk of a Positive Examination Result	Absolute Risk of a Positive Examination Result per 1000 Newborns With Risk Factors
All newborns	...	11.5
Boys	1.0	4.1
Girls	4.6	19
Positive family history	1.7	
Boys	...	6.4
Girls	...	32
Breech presentation	7.0	
Boys	...	29
Girls	...	133

TABLE 2. Newborn Strategy*

Outcome	Orthopaedist PE	Pediatrician PE	Ultrasonography
DDH in newborn	12	8.6	25
DDH at ~6 mo of age	.1	.45	.28
DDH at 12 mo of age or more	.16	.33	.1
AVN at 12 mo of age	.06	.1	.1

* PE indicates physical examination. Outcome per 1000 infants initially screened.

others, a pediatrician, and in still others, a physiotherapist. In addition, screening has been performed by ultrasonography. In assessing the expected effect of each strategy, we estimated the newborn DDH rates, the mid-term DDH rates, and the late-term DDH rates for each of the 3 strategies, as shown in Table 2. We also estimated the rate of AVN for DDH treated before 2 months of age (2.5/1000 treated) and after 2 months of age (109/1000 treated). We could not distinguish the AVN rates for children treated between 2 and 12 months of age from those treated later. Table 2 gives these data. The total cases of AVN per strategy are calculated, assuming that all infants with positive examination results are treated.

Table 2 shows that a strategy using pediatricians to screen newborns would give the lowest newborn rate but the highest mid- and late-term DDH rates. To assess how much better an ultrasonography-only screening strategy would be, we could calculate a cost-effectiveness ratio. In this case, the "cost" of ultrasonographic screening is the number of "extra" newborn cases that probably include children who do not need to be treated. (The cost from AVN is the same in the 2 strategies.) By using these cases as the cost and the number of later cases averted as the effect, a ratio is obtained of 71 children treated neonatally because of a positive ultrasonographic screen for each later case averted. Because this number is high, and because the presumption of better late-term efficacy is based on a single study, we do not recommend ultrasonographic screening at this time.

RECOMMENDATIONS AND NOTES TO ALGORITHM (Fig 1)

1. **All newborns are to be screened by physical examination.** The evidence† for this recommendation is good. The expert consensus‡ is strong. Although initial screening by orthopaedists§ would be optimal (Table 2), it is doubtful that if widely practiced, such a strategy would give the same good results as those published from pediatric orthopaedic research centers. **It is recommended that screening be done by a properly trained health care provider** (eg, physician, pediatric nurse practitioner, physician assistant, or physical therapist). (Evidence for this recommendation is strong.) A number of studies performed by properly trained nonphysicians report results

indistinguishable from those performed by physicians.³⁶ The examination after discharge from the neonatal intensive care unit should be performed as a newborn examination with appropriate screening. **Ultrasonography of all newborns is not recommended.** (Evidence is fair; consensus is strong.) Although there is indirect evidence to support the use of ultrasonographic screening of all newborns, it is not advocated because it is operator-dependent, availability is questionable, it increases the rate of treatment, and interobserver variability is high. There are probably some increased costs. We considered a strategy of "no newborn screening." This arm is politically indefensible because screening newborns is inherent in pediatrician's care. The technical report details this limb through decision analysis. Regardless of the screening method used for the newborn, DDH is detected in 1 in 5000 infants at 18 months of age.³ The evidence and consensus for newborn screening remain strong.

Newborn Physical Examination and Treatment

2. **If a positive Ortolani or Barlow sign is found in the newborn examination, the infant should be referred to an orthopaedist.** Orthopaedic referral is recommended when the Ortolani sign is unequivocally positive (a clunk). Orthopaedic referral is not recommended for any softly positive finding in the examination (eg, hip click without dislocation). The precise time frame for the newborn to be evaluated by the orthopaedist cannot be determined from the literature. However, the literature suggests that the majority of "abnormal" physical findings of hip examinations at birth (clicks and clunks) will resolve by 2 weeks; therefore, consultation and possible initiation of treatment are recommended by that time. The data recommending that all those with a positive Ortolani sign be referred to an orthopaedist are limited, but expert panel consensus, nevertheless, was strong, because pediatricians do not have the training to take full responsibility and because true Ortolani clunks are rare and their management is more appropriately performed by the orthopaedist.

If the results of the physical examination at birth are "equivocally" positive (ie, soft click, mild asymmetry, but neither an Ortolani nor a Barlow sign is present), then a follow-up hip examination by the pediatrician in 2 weeks is recommended. (Evidence is good; consensus is strong.) The available data suggest that most clicks resolve by 2 weeks and that these "benign hip clicks" in the newborn period do

†In this guideline, evidence is listed as good, fair, or poor based on the methodologist's evaluation of the literature quality. (See the Technical Report.)

‡Opinion or consensus is listed as *strong* if opinion of the expert panel was unanimous or *mixed* if there were dissenting points of view.

§In this guideline, the term *orthopaedist* refers to an orthopaedic surgeon with expertise in pediatric orthopaedic conditions.

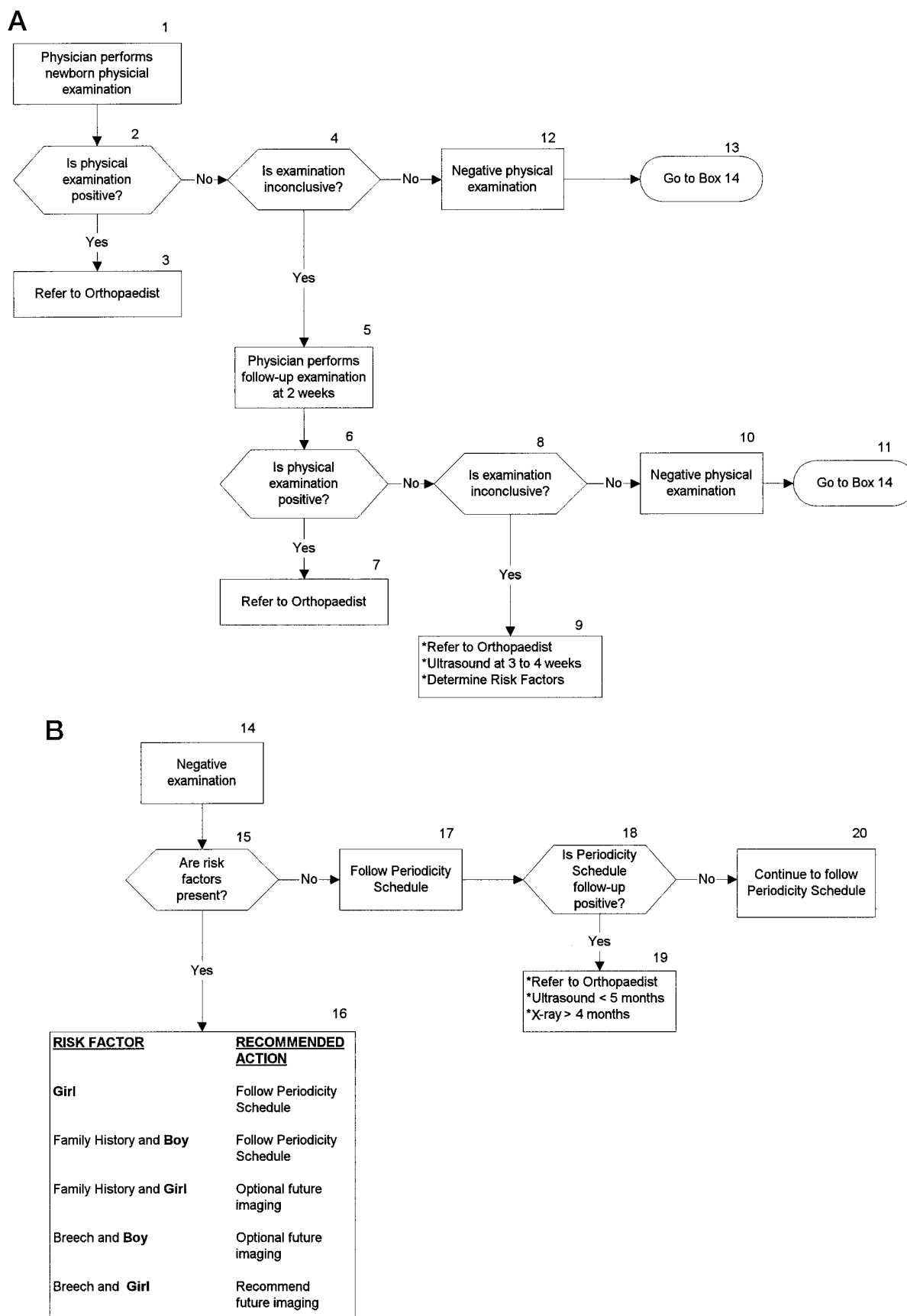


Fig 1. Screening for developmental hip dysplasia—clinical algorithm.

not lead to later hip dysplasia.^{9,17,28,37} Thus, for an infant with softly positive signs, the pediatrician should reexamine the hips at 2 weeks before making referrals for orthopaedic care or ultrasonography. We recognize the concern of pediatricians about adherence to follow-up care regimens, but this concern regards all aspects of health maintenance and is not a reason to request ultrasonography or other diagnostic study of the newborn hips.

3. **If the results of the newborn physical examination are positive (ie, presence of an Ortolani or a Barlow sign), ordering an ultrasonographic examination of the newborn is not recommended.** (Evidence is poor; opinion is strong.) Treatment decisions are not influenced by the results of ultrasonography but are based on the results of the physical examination. The treating physician may use a variety of imaging studies during clinical management. **If the results of the newborn physical examination are positive, obtaining a radiograph of the newborn's pelvis and hips is not recommended** (evidence is poor; opinion is strong), because they are of limited value and do not influence treatment decisions.

The use of triple diapers when abnormal physical signs are detected during the newborn period is not recommended. (Evidence is poor; opinion is strong.) Triple diaper use is common practice despite the lack of data on the effectiveness of triple diaper use; and, in instances of frank dislocation, the use of triple diapers may delay the initiation of more appropriate treatment (such as with the Pavlik harness). Often, the primary care pediatrician may not have performed the newborn examination in the hospital. The importance of communication cannot be overemphasized, and triple diapers may aid in follow-up as a reminder that a possible abnormal physical examination finding was present in the newborn.

2-Week Examination

4. **If the results of the physical examination are positive (eg, positive Ortolani or Barlow sign) at 2 weeks, refer to an orthopaedist.** (Evidence is strong; consensus is strong.) Referral is urgent but is not an emergency. Consensus is strong that, as in the newborn, the presence of an Ortolani or Barlow sign at 2 weeks warrants referral to an orthopaedist. An Ortolani sign at 2 weeks may be a new finding or a finding that was not apparent at the time of the newborn examination.
5. **If at the 2-week examination the Ortolani and Barlow signs are absent but physical findings raise suspicions, consider referral to an orthopaedist or request ultrasonography at age 3 to 4 weeks.** Consensus is mixed about the follow-up for softly positive or equivocal findings at 2 weeks of age (eg, adventitious click, thigh asymmetry, and apparent leg length difference). Because it is necessary to confirm the status of the hip joint, the pediatrician can consider referral to an orthopaedist or for ultrasonography if the constellation of physical findings raises a high level of suspicion.

However, if the physical findings are minimal, continuing follow-up by the periodicity schedule with focused hip examinations is also an option, provided risk factors are considered. (See "Recommendations" 7 and 8.)

6. **If the results of the physical examination are negative at 2 weeks, follow-up is recommended at the scheduled well-baby periodic examinations.** (Evidence is good; consensus is strong.)
7. **Risk factors. If the results of the newborn examination are negative (or equivocally positive), risk factors may be considered.**^{13,21,38-41} Risk factors are a study of thresholds to act.⁴² Table 1 gives the risk of finding a positive Ortolani or Barlow sign at the time of the initial newborn screening. If this examination is negative, the absolute risk of there being a true dislocated hip is greatly reduced. Nevertheless, the data in Table 1 may influence the pediatrician to perform confirmatory evaluations. Action will vary based on the individual clinician. The following recommendations are made (evidence is strong; opinion is strong):
 - **Girl** (newborn risk of 19/1000). When the results of the newborn examination are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age.
 - **Infants with a positive family history of DDH** (newborn risk for boys of 9.4/1000 and for girls, 44/1000). When the results of the newborn examination in boys are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age. In girls, the absolute risk of 44/1000 may exceed the pediatrician's threshold to act, and imaging with an ultrasonographic examination at 6 weeks of age or a radiograph of the pelvis at 4 months of age is recommended.
 - **Breech presentation** (newborn risk for boys of 26/1000 and for girls, 120/1000). **For negative or equivocally positive newborn examinations, the infant should be reevaluated at regular intervals (according to the periodicity schedule) if the examination results remain negative.** Because an absolute risk of 120/1000 (12%) probably exceeds most pediatricians' threshold to act, imaging with an ultrasonographic examination at 6 weeks of age or with a radiograph of the pelvis and hips at 4 months of age is recommended. In addition, because some reports show a high incidence of hip abnormalities detected at an older age in children born breech, this imaging strategy remains an option for all children born breech, not just girls. These hip abnormalities are, for the most part, inadequate development of the acetabulum. Acetabular dysplasia is best found by a radiographic examination at 6 months of age or older. A

suggestion of poorly formed acetabula may be observed at 6 weeks of age by ultrasonography, but the best study remains a radiograph performed closer to 6 months of age. Ultrasonographic newborn screening of all breech infants will not eliminate the possibility of later acetabular dysplasia.

8. **Periodicity. The hips must be examined at every well-baby visit according to the recommended periodicity schedule for well-baby examinations (2–4 days for newborns discharged in less than 48 hours after delivery, by 1 month, 2 months, 4 months, 6 months, 9 months, and 12 months of age).** If at any time during the follow-up period DDH is suspected because of an abnormal physical examination or by a parental complaint of difficulty diapering or abnormal appearing legs, the pediatrician must confirm that the hips are stable, in the sockets, and developing normally. Confirmation can be made by a focused physical examination when the infant is calm and relaxed, by consultation with another primary care pediatrician, by consultation with an orthopaedist, by ultrasonography if the infant is younger than 5 months of age, or by radiography if the infant is older than 4 months of age. (Between 4 and 6 months of age, ultrasonography and radiography seem to be equally effective diagnostic imaging studies.)

DISCUSSION

DDH is an important term because it accurately reflects the biologic features of the disorder and the susceptibility of the hip to become dislocated at various times. Dislocated hips always will be diagnosed later in infancy and childhood because not every dislocated hip is detectable at birth, and hips continue to dislocate throughout the first year of life. Thus, this guideline requires that the pediatrician follow *a process of care for the detection of DDH*. The process recommended for early detection of DDH includes the following:

- Screen all newborns' hips by physical examination.
- Examine all infants' hips according to a periodicity schedule and follow-up until the child is an established walker.
- Record and document physical findings.
- Be aware of the changing physical examination for DDH.
- If physical findings raise suspicion of DDH, or if parental concerns suggest hip disease, confirmation is required by expert physical examination, referral to an orthopaedist, or by an age-appropriate imaging study.

When this process of care is followed, the number of dislocated hips diagnosed at 1 year of age should be minimized. However, the problem of late detection of dislocated hips will not be eliminated. The results of screening programs have indicated that 1 in 5000 children have a dislocated hip detected at 18 months of age or older.³

TECHNICAL REPORT

The Technical Report is available from the American Academy of Pediatrics from several sources. The Technical Report is published in full-text on *Pediatrics electronic pages*. It is also available in a compendium of practice guidelines that contains guidelines and evidence reports together. The objective was to create a recommendation to pediatricians and other primary care providers about their role as screeners for detecting DDH. The patients are a theoretical cohort of newborns. A model-based method using decision analysis was the foundation. Components of the approach include:

- Perspective: primary care provider
- Outcomes: DDH and AVN
- Preferences: expected rates of outcomes
- Model: influence diagram assessed from the subcommittee and from the methodology team with critical feedback from the subcommittee
- Evidence sources: Medline and EMBase (detailed in "Methods" section)
- Evidence quality: assessed on a custom, subjective scale, based primarily on the fit of the evidence in the decision model

The results are detailed in the "Methods" section. Based on the raw evidence and Bayesian hierarchical meta-analysis,^{34,35} estimates for the incidence of DDH based on the type of screener (orthopaedist vs pediatrician); the odds ratio for DDH given risk factors of sex, family history, and breech presentation; and estimates for late detection and AVN were determined and are detailed in the "Methods" section and in Tables 1 and 2.

The decision model (reduced based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ in pediatric expertise, the supply of pediatric orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is statistically insignificant, we conclude that pediatric screening is to be recommended. The place for ultrasonography in the screening process remains to be defined because of the limited data available regarding late diagnosis in ultrasonography screening to permit definitive recommendations.

These data could be used by others to refine the conclusion based on costs, parental preferences, or physician style. Areas for research are well defined by our model-based method. All references are in the Technical Report.

RESEARCH QUESTIONS

The quality of the literature suggests many areas for research, because there is a paucity of randomized clinical trials and case-controlled studies. The following is a list of possibilities:

1. Minimum diagnostic abilities of a screener. Although there are data for pediatricians in general, few, if any, studies evaluated the abilities of an individual examiner. What should the minimum

sensitivity and specificity be, and how should they be assessed?

2. Intercurrent screening. There were few studies on systemic processes for screening after the newborn period.^{2,43,44} Although several studies assessed postneonatal DDH, the data did not specify how many examinations were performed on each child before the abnormal result was found.
3. Trade-offs. Screening always results in false-positive results, and these patients suffer the adverse effects of therapy. How many unnecessary AVNs are we—families, physicians, and society—willing to tolerate from a screening program for every appropriately treated infant in whom late DDH was averted? This assessment depends on people's values and preferences and is not strictly an epidemiologic issue.
4. Postneonatal DDH after ultrasonographic screening. Although we concluded that ultrasonographic screening did not result in fewer diagnoses of postneonatal DDH, that conclusion was based on only 1 study.³⁶ Further study is needed.
5. Cost-effectiveness. If ultrasonographic screening reduces the number of postneonatal DDH diagnoses, then there will be a cost trade-off between the resources spent up front to screen everyone with an expensive technology, as in the case of ultrasonography, and the resources spent later to treat an expensive adverse event, as in the case of physical examination-based screening. The level at which the cost per case of postneonatal DDH averted is no longer acceptable is a matter of social preference, not of epidemiology.

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ADDENDUM TO REFERENCES FOR THE DDH GUIDELINE

New information is generated constantly. Specific details of this report must be changed over time.

New articles (additional articles 1–7) have been published since the completion of our literature search and construction of this Guideline. These articles taken alone might seem to contradict some of the Guideline's estimates as detailed in the article and in the Technical Report. However, taken in context with the literature synthesis carried out for the construction of this Guideline, our estimates remain intact and no conclusions are obviated.

ADDITIONAL ARTICLES

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Technical Report Summary: Developmental Dysplasia of the Hip Practice Guideline

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For the complete technical report, including tables, figures, and references, please see the companion CD-ROM.

ABSTRACT

Objective. To create a recommendation for pediatricians and other primary care providers about their role as screeners for detecting developmental dysplasia of the hip (DDH) in children.

Patients. Theoretical cohorts of newborns.

Method. Model-based approach using decision analysis as the foundation. Components of the approach include the following:

Perspective: Primary care provider.

Outcomes: DDH, avascular necrosis of the hip (AVN).

Options: Newborn screening by pediatric examination; orthopaedic examination; ultrasonographic examination; orthopaedic or ultrasonographic examination by risk factors. Intercurrent health supervision-based screening.

Preferences: 0 for bad outcomes, 1 for best outcomes.

Model: Influence diagram assessed by the Subcommittee and by the methodology team, with critical feedback from the Subcommittee.

Evidence Sources: Medline and EMBASE search of the research literature through June 1996. Hand search of sentinel journals from June 1996 through March 1997. Ancestor search of accepted articles.

Evidence Quality: Assessed on a custom subjective scale, based primarily on the fit of the evidence to the decision model.

Results. After discussion, explicit modeling, and critique, an influence diagram of 31 nodes was created. The computer-based and the hand literature searches found 534 articles, 101 of which were reviewed by 2 or more readers. Ancestor searches of these yielded a further 17 articles for evidence abstraction. Articles came from around the globe, although primarily Europe, British Isles, Scandinavia, and their descendants. There were 5 controlled trials, each with a sample size less than 40. The remainder were case series. Evidence was available for 17 of the desired 30 probabilities. Evidence quality ranged primarily between one third and two thirds of the maximum attainable score (median: 10–21; interquartile range: 8–14).

Based on the raw evidence and Bayesian hierarchical meta-analyses, our estimate for the incidence of DDH revealed by physical examination performed by pediatricians is 8.6 per 1000; for orthopaedic screening, 11.5; for ultrasonography, 25. The odds ratio for DDH, given breech delivery, is 5.5; for female sex, 4.1; for positive family history, 1.7, although this last factor is not statistically significant. Postneonatal cases of DDH were divided into mid-term (younger than 6 months of age) and late-term (older than 6 months of age). Our estimates for the mid-term rate for screening by pediatricians is 0.34/1000 children screened; for orthopaedists, 0.1; and for ultrasonography, 0.28. Our estimates for late-term DDH rates are 0.21/1000 newborns screened by pediatricians; 0.08, by orthopaedists; and 0.2 for ultrasonography. The rates of AVN for children referred before 6 months of age is estimated at 2.5/1000 infants referred. For those referred after 6 months of age, our estimate is 109/1000 referred infants.

The decision model (reduced, based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ, the supply of orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is statistically insignificant, we conclude that pediatric screening is to be recommended. The place of ultrasonography in the screening process remains to be defined because there are too few data about postneonatal diagnosis by ultrasonographic screening to permit definitive recommendations. These data could be used by others to refine the conclusions based on costs, parental preferences, or physician style. Areas for research are well defined by our model-based approach. *Pediatrics* 2000;105(4). URL: <http://www.pediatrics.org/cgi/content/full/105/4/e57>; keywords: *developmental dysplasia of the hip, avascular necrosis of the hip, newborn*.

I. GUIDELINE METHODS

A. Decision Model

The steps required to build the model were taken with the Subcommittee as a whole, with individuals in the group, and with members of the methodology team. Agreement on the model was sought from the Subcommittee as a whole during face-to-face meetings.

1. Perspective

Although there are a number of perspectives to take in this problem (parental, child's, societal, and payer's), we opted for the view of the practicing clinician: What are the clinician's obligations, and what is the best strategy for the clinician? This choice of perspective meant that the focus would be on screening for developmental dysplasia of the hip (DDH) and obviated the need to review the evidence for efficacy or effectiveness of specific strategies.

2. Context

The target child is a full-term newborn with no obvious orthopaedic abnormalities. Children with such findings would be referred to an orthopaedist, obviating the need for a practice parameter.

3. Options

We focused on the following options: screening by physical examination (PE) at birth by a pediatrician, orthopaedist, or other care provider; ultrasonographic screening at birth; and episodic screening during health supervision. Treatment options are not included.

We also included in our model a wide range of options for managing the screening process during the first year of life when the newborn screening was negative.

4. Outcomes

Our focus is on dislocated hips at 1 year of age as the major morbidity of the disease and on avascular necrosis of the hip (AVN), as the primary sentinel complication of DDH therapy.

Ideally, we would have a “gold standard” that would define DDH at any point in time, much as cardiac output can be obtained from a pulmonary-artery catheter. However, no gold standard exists. Therefore, we defined our outcomes in terms of the process of care: a pediatrician and an ultrasonographer perform initial or confirmatory examinations and refer the patient, whereas the orthopaedist treats the patient. It is the treatment that has the greatest effect on postneonatal DDH or on complications, so we focus on that intermediate outcome, rather than the orthopaedist’s stated diagnosis. We operationalized the definitions of these outcomes for use in abstracting the data from articles. A statement that a “click” was found on PE was considered to refer to an intermediate result, unless the authors defined their “click” in terms of our definition of a positive examination. Dynamic ultrasonographic examinations include those of Harcke et al, and static refers primarily to that of Graf. The radiologic focus switches from ultrasonography to plain radiographs after 4 months of age, in keeping with the development of the femoral head.

5. Decision Structure

We used an influence diagram to represent the decision model. In this representation, nodes refer to actions to be taken or to states of the world (the patient) about which we are uncertain. We devoted substantial effort to the construction of a model that balanced the need to represent the rich array of possible screening pathways with the need to be parsimonious. We constructed the master influence diagram and determined its construct validity through consensus by the Subcommittee before data abstraction. However, the available evidence could specify only a portion of the diagram. The missing components suggest research questions that need to be posed.

6. Probabilities

The purpose of the literature review was to provide the probabilities required by the decision model. The initial number of individual probabilities was 55. (Sensitivity and specificity for a single truth-indicator pair are counted as a single probability because they are garnered from the same table.) Although this is a large number of parameters, the structure of the model helped the team of readers. As 1 reader said, referring to the influence diagram, “Because we did the picture together, it was easy to find the parameters.” What follows are some operational rules for matching the data to our parameters. The list is not complete. If an orthopaedic clinic worked at case finding, we used our judgment to determine whether to accept such reports as representing a population incidence.

Risk factors were included generally only if a true control group was used for comparison. For postneonatal diagnoses, no study we reviewed included the examination of all children without DDH, say, 1 year of age, so there is always the possibility of missed cases (false-negative diagnoses) in the screen,

which leads to a falsely elevated estimate of the denominator. For studies originating in referral clinics, the data on the reasons for referrals were not usable for our purposes.

7. Preferences

Ideally, we would have cost data for the options, as well as patient data on the human burden of therapy and of DDH itself. We have deferred these assessments to later research. Therefore, we assigned a preference score of 0 to DDH at 1 year of age and 1 to its absence; for AVN, we assigned 0 for presence at 1 year of age and 1 for absence at 1 year of age.

B. Literature Review

For the literature through May 1995, the following sources were searched: Books in Print, CAT-LINE, Current Contents, EMBASE, Federal Research in Progress, Health Care Standards, Health Devices Alerts, Health Planning and Administration, Health Services/Technology Assessment, International Health Technology Assessment, and Medline. Medline and EMBASE were searched through June 1996. The search terms used in all databases included the following: hip dislocation, congenital; hip dysplasia; congenital hip dislocation; developmental dysplasia; ultrasonography/adverse effects; and osteonecrosis. Hand searches of leading orthopaedic journals were performed for the issues from June 1996 to March 1997. The bibliographies of journals accepted for use in formulating the practice parameter also were perused.

The titles and the abstracts were then reviewed by 2 members of the methodology team to determine whether to accept or reject the articles for use. Decisions were reviewed by the Subcommittee, and conflicts were adjudicated. Similarly, articles were read by pairs of reviewers; conflicts were resolved in discussion.

The focus of the data abstraction process was on data that would provide evidence for the probabilities required by the decision model.

As part of the literature abstraction process, the evidence quality in each article was assessed. The scoring process was based on our decision model and involved traditional epidemiologic concerns, like outcome definition and bias of ascertainment, as well as influence-diagram-based concerns, such as how well the data fit into the model.

Cohort definition: Does the cohort represented by the denominator in the study match a node in our influence diagram? Does the cohort represented by the numerator match a node in our influence diagram? The closer the match, the more confident we are that the reported data provide good evidence of the conditional probability implied by the arrow between the corresponding nodes in the influence diagram.

Path: Does the implied path from denominator to numerator lead through 1 or more nodes of the influence diagram? The longer the path, the more likely that uncontrolled biases entered into the study, making us less confident about accepting the raw data as a conditional probability in our model. Assignment and comparison: Was there a control group? How was assignment made to

experimental or control arms? A randomized, controlled study provides the best quality evidence.

Follow-up: Were patients with positive and negative initial findings followed up? The best studies should have data on both.

Outcome definition: Did the language of the outcome definitions (PE, orthopaedic examination, ultrasonography, and radiography) match ours, and, in particular, were PE findings divided into 3 categories or 2? The closer the definition to ours, the more we could pool the data. Studies with only 2 categories do not help to distinguish clicks from “clunks.”

Ascertainment: When the denominator represented more than 1 node, to what degree was the denominator a mix of nodes? The smaller the contamination, the more confident we were that the raw data represented a desired conditional probability.

Results: Did the results fill an entire table or were data missing? This is related to the follow-up category but is more general.

C. Synthesis of Evidence

There are 3 levels of evidence synthesis.

1. Listing evidence for individual probabilities
2. Summarizing evidence across probabilities
3. Integrating the pooled evidence for individual probabilities into the decision model

A list of evidence for an individual probability (or arc) is called an *evidence table* and provides the reader a look at the individual pieces of data. The probabilities are summarized in 3 ways: by averaging, by averaging weighted by sample size (pooled), and by meta-analysis. We chose Bayesian meta-analytic techniques, which allow the representation of *prior belief* in the evidence and provide an explicit portrayal of the uncertainty of our conclusions. The framework we used was that of a hierarchical Bayesian model, similar to the random effects model in traditional meta-analysis. In this hierarchical model, each study has its own parameter, which, in turn, is sampled from a wider population parameter. Because there are 2 stages (ie, population to sample and sample to observation), and, therefore, the population parameter of interest is more distant from the data, the computed estimates in the population parameters are, in general, less certain (wider confidence interval) than simply pooling the data across studies. This lower certainty is appropriate in the DDH content area because the studies vary so widely in their raw estimates because of the range in time and geography over which they were performed. In the Bayesian model, the observations were assumed to be Poisson distributed, given the study DDH rates. Those rates, in turn, were assumed to be Gamma distributed, given the population rate. The prior belief on that rate was set as Gamma (α , β), with mean α/β , and variance α/β^2 (as defined in the BUGS software). In this parameterization, α has the semantics closest to that of location, and β has the semantics of certainty: the higher its value, the narrower the distribution and the more certain we are of the estimate. The parameter, α , was modeled as Exponential (1), and β , as Gamma (0.01, 1), with a mean of 0.01. Together, these correspond to a prior belief in the rate of a mean of 100 per

1000, and a standard deviation (SD) of 100, representing ignorance of the true rate.

As an example of interpretation, for pediatric newborn screening, the posterior α was 1.46, and the posterior β was 0.17, to give a posterior rate of 8.6/1000, with a variance of 50, or an SD of 7.1. The value of β rose from 0.01 to 0.17, indicating a higher level of certainty.

The Bayesian confidence interval is the narrowest interval that contains 95% of the area under the posterior-belief curve. The confidence interval for the prior curve is 2.53 to 370. The confidence interval for the posterior curve is 0.25 to 27.5, a significant shrinking and increase in certainty but still broad.

The model for the odds ratios is more complicated and is based on the Oxford data set and analysis in the BUGS manual.

D. Thresholds

In the course of discussions about results, the Subcommittee was surveyed about the acceptable risks of DDH for different levels of interventions.

E. Recommendations

Once the evidence and thresholds were obtained, a decision tree was created from the evidence available and was reviewed by the Subcommittee. In parallel, a consensus guideline (flowchart) was created. The Subcommittee evaluated whether evidence was available for links within the guidelines, as well as their strength of consensus. The decision tree was evaluated to check consistency of the evidence with the conclusions.

F. “Cost”-Effectiveness Ratios

To integrate the results, we defined cost-effectiveness ratios, in which cost was excess neonatal referrals or excess cases of AVNs, and *effectiveness* was a decrease in the number of later cases. The decision tree from section E (“Recommendations”) was used to calculate the expected outcomes for each of pediatric, orthopaedic, and ultrasonographic strategies. Pediatric strategy was used as the baseline, because its neonatal screening rate was the lowest. The cost-effectiveness ratios then were calculated as the quotient of the difference in cost and the difference in effect.

RESULTS

A. Articles

The peak number of articles is for 1992, with 10 articles. The articles are from sites all over the world, although the Nordic, Anglo-Saxon, and European communities and their descendants are the most represented.

B. Evidence

By traditional epidemiologic standards, the quality of evidence in this set of articles is uniformly low. There are few controlled trials and few studies in which infants with negative results on their newborn examinations are followed up. (A number of studies attempted to cover all possible places where an affected child might have been ascertained.)

We found data on all chance nodes, for a total of 298 distinct tables. *Decision* nodes were poorly represented: beyond the neonatal strategy, there were almost no

data clarifying the paths for the diagnosis children after the newborn period. Thus, although communities like those in southeast Norway have a postnewborn screening program, it is unclear what the program was, and it was unclear how many examination results were normal before a child was referred to an orthopaedist.

The mode is a score of 10, achieved in 16 articles. The median is 9.9, with an interquartile range of 8 to 14, suggesting that articles with scores below 8 are poor sources of evidence. Note that the maximum achievable quality score is 21, so half the articles do not achieve half the maximum quality score.

Graphing evidence quality against publication year suggests an improvement in quality over time, as shown in Fig 9, but the linear fit through the data is statistically indistinguishable from a flat line. (A nonparametric procedure yields the same conclusion).

The studies include 5 in which a comparative arm was designed into the study. The remainder are divided between prospective and retrospective studies. Surprisingly, the evidence quality is not higher in the former than in the latter (data not shown).

Of the 298 data tables, half the data tables relate to the following:

- probabilities of DDH in different screening strategies
- relative risk of DDH, given risk factors
- the incidence of postneonatal DDH, and
- the incidence of AVN.

The remainder of our discussion will focus on these probabilities.

C. Evidence Tables

The evidence table details are found in the appendix of the full technical report.

1. Newborn Screening

a. Pediatric Screening

There were 51 studies, providing 57 arms, for pediatric screening. However, of these, 17 were unclear on how the intermediate examinations were handled, and, unsurprisingly, their observed rates of positivity (clicks) were much higher than the studies that distinguished 3 categories, as we had specified. Therefore, we included only the 34 studies that used 3 categories.

For pediatric screening, the rate is about 8 positive cases per 1000 examinations. The rates are distributed almost uniformly between 0 and 20 per 1000. All studies represent a large experience: a total of 2 149 972 subjects. Although their methods may not have been the best, the studies demand attention simply because of their size.

In looking for covariates or confounding variables, we studied the relationship between positivity rate and the independent variables, year of publication, evidence quality, and sample size. Year and evidence quality show a positive effect: the higher the year (slope: 0.2; $P = .018$) or evidence quality (slope: 0.6; $P = .046$), the higher the observed rate. A model with both factors has evidence that suggests that most of the effect is in the factor, year

(slope for year: 0.08; $P = .038$; slope for quality of evidence: 0.49; $P = .09$). Note that a regression using evidence quality is improper, because our evidence scale is not properly ratio (eg, the distance between 6 and 7 is not necessarily equivalent to the distance between 14 and 15), but the regression is a useful exploratory device.

b. Orthopaedic Screening

Evidence was found in 25 studies. Three studies provided 2 arms each.

The positivity rate for orthopaedic screening is between 7 and 11/1000. One outlier study, with an observed rate of more than 300/1000, skews the unweighted and meta-analytic averages. The estimate (between 7.1 and 11) is just below that of pediatric screening and is statistically indistinguishable. Note, however, that a fair number of studies have rates near 22/1000 or higher.

Unlike with pediatric screening, there are no correlations with other factors.

c. Ultrasonographic Screening

Evidence was found in 17 studies, each providing a single arm.

The rate for ultrasonographic screening is 20/1000 or more. Although the estimates are sensitive to pooling and to the outlier, the positivity rate is clearly higher than in either PE strategy. There are no correlating factors. In particular, studies that use the Graf method 2 or those that use the method of Harcke et al show comparable rates.

2. Postneonatal Cases

We initially were interested in all postneonatal diagnoses of DDH. However, the literature did not provide data within the narrow time frames initially specified for our model. Based on the data that were available, we considered 3 classes of postneonatal DDH: DDH diagnosed after 12 months of age ("late-term"), DDH diagnosed between 6 and 12 months of age ("mid-term"), and DDH diagnosed before 6 months of age. There were few data for the latter group, which often was combined with the newborn screening programs. Therefore, we collected data on only the first 2 groups.

a. After Pediatric Screening

Evidence was found in 24 studies. The study by Dunn and O'Riordan provided 2 arms. It is difficult to discern an estimate rate for mid-term DDH, because the study by Czeizel et al is such an outlier, with a rate of 3.73/1000, and because the weighted and unweighted averages also differ greatly. The meta-analytic estimate of 0.55/1000 seems to be an upper limit.

The late-term rate is easier to estimate at ~0.3/1000. Although it is intuitive that the late-term rate should be lower than the mid-term rate, our data do not allow us to draw that conclusion.

b. After Orthopaedic Screening

There were only 4 studies. The rates were comparable for mid- and late-term: 0.1/1000 newborns. A meta-analytic estimate was not calculated.

c. After Ultrasonographic Screening

Only 1 study, by Rosendahl et al is available; it reported rates for infants with and without initial risk factors (eg, family history and breech presentation). The mid-term rate was 0.28/1000 newborns in the non-risk group, and the late-term rate was 0/1000 in the same group.

3. AVN After Treatment

For these estimates, we grouped together all treatments, because from the viewpoint of the referring primary care provider, orthopaedic treatment is a "black box." A literature synthesis that teased apart the success and complications of particular *therapeutic* strategies is beyond the scope of the present study.

The complication rate should depend only on the age of the patient at time of orthopaedic referral and on the type of treatment received. We report on the complication rates for children treated before and after 12 months of age.

a. After Early Referral

There were 17 studies providing evidence. Infants were referred to orthopaedists during the newborn period in each study except 2. In the study by Pool et al, infants were referred during the newborn period and before 2 months of age; in the study by Sochart and Paton, infants were referred between 2 weeks and 2 months of age.

The range of AVN rates per 1000 infants referred was huge, from 0 to 123. The largest rate occurred in the study by Pool et al, a sample-based study that included later referrals. Its evidence quality was 8, within the 7 to 13 interquartile range of the other studies in this group. As in earlier tables, the meta-analytic estimate lies between the average and weighted (pooled) average of the studies.

b. After Later Referral

Evidence was obtained from 6 studies. Some of the studies included children referred during the newborn period or during the 2-week to 2-month period, but even in these, the majority of infants were referred later during the first year of life.

There were no outlier rates, although the highest rate (216/1000 referred children) occurred in the study with the oldest referred children in the sample with children referred who were older than 12 months of age. One study contributed 5700 patients to the analysis, more than half of the 9270 total, so its AVN rate of 27/1000 brought the unweighted rate of 116/1000 to 54. A meta-analytic estimate was not computed.

4. Risk Factors

A number of factors are known to predispose infants to DDH. We sought evidence for 3 of these: sex, obstetrical position at birth, and family history. Studies were included in these analyses only if a

control group could be ascertained from the available study data.

The key measure is the odds ratio, an estimate of the relative risk. The meaning of the odds ratio is that if the DDH rate for the control group is known, then the DDH rate for the at-risk group is the product of the control-group DDH rate and the odds ratio for the risk factor. An odds ratio statistically significantly greater than 1 indicates that the factor is a risk factor.

The Bayesian meta-analysis produces estimates between the average of the odds ratios and the pooled odds ratio and is, therefore, the estimate we used in our later analyses.

a. Female

The studies were uniform in discerning a risk to girls ~4 times that of boys for being diagnosed with DDH. This risk was seen in all 3 screening environments.

b. Breech

The studies for breech also were confident in finding a risk for breech presentation, on the order of fivefold. One study found breech presentation to be protective, but the study was relatively small and used ultrasonography rather than PE as its outcome measure.

c. Family History

Although some studies found family history to be a risk factor, the range was wide. The confidence intervals for the pooled odds ratio and for the Bayesian analysis contained 1.0, suggesting that family history is *not* an independent risk factor for DDH. However, because of traditional concern with this risk factor, we kept it in our further considerations.

D. Evidence Summary and Risk Implications

To bring all evidence tables together, we constructed a summary table, which contains the estimates we chose for our recommendations. The intervals are asymmetric, in keeping with the intuition that rates near zero cannot be negative, but certainly can be very positive.

Risk factors are based on the pediatrician population rate of 8.6 labeled cases of DDH per 1000 infants screened. In the Subcommittee's discussion, 50/1000 was a cutoff for automatic referral during the newborn period. Hence, girls born in the breech position are classified in a separate category for newborn strategies than infants with other risk factors.

If we use the orthopaedists' rate as our baseline, numbers suggest that boys without risks or those with a family history have the lowest risk; girls without risks and boys born in the breech presentation have an intermediate risk; and girls with a positive family history, and especially girls born in the breech presentation, have the highest risks. Guidelines that consider risk factors should follow these risk profiles.

E. Decision Recommendations

With the evidence synthesized, we can estimate the expected results of the target newborn strategies for post-neonatal DDH and AVN.

If a case of DDH is observed in an infant with an initially negative result of screening by an orthopaedist in a newborn screening program, that case is “counted” against the orthopaedist strategy.

The numbers are combined using a simple decision tree, which is not the final tree represented by our influence diagram but is a tree that is supported by our evidence. The results show that pediatricians diagnose fewer newborns with DDH and perhaps have a higher postneonatal DDH rate than orthopaedists but one that is comparable to ultrasonography (acknowledging that our knowledge of postneonatal DDH revealed by ultrasonographic screening is limited). The AVN rates are comparable with pediatrician and ultrasonographic screening and less than with orthopaedist screening.

F. Cost-Effectiveness Ratios

In terms of excess neonatal referrals, the ratios suggest that there is a trade-off: for every case that these strategies detect beyond the pediatric strategy, they require more than 7000 or 16 000 extra referrals, respectively.

DISCUSSION

A. Summary

We derived 298 evidence tables from 118 studies culled from a larger set of 624 articles. Our literature review captured most in our model-based approach, if not all, of the past literature on DDH that was usable. The decision model (reduced based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ, the supply of orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is relatively small, we conclude that pediatric screening is to be recommended. The place of ultrasonography in the screening process remains to be defined because there are too few data about postneonatal diagnosis by ultrasonographic screening to permit definitive recommendations.

Our conclusions are tempered by the uncertainties resulting from the wide range of the evidence. The confidence intervals are wide for the primary parameters. The uncertainties mean that, even with all the evidence collected from the literature, we are left with large doubts about the values of the different parameters.

Our data do not bear directly on the issue about the earliest point that any patient destined to have DDH will show signs of the disease. Our use of the terms *mid-term* and *late-term* DDH addresses that ignorance.

Our conclusions about other areas of the full decision model are more tentative because of the paucity of data about the effectiveness of periodicity examinations. Even the studies that gave data on mid-term and late-term case findings by pediatricians were sparse in their details about how the screening was instituted, maintained, or followed up.

Our literature search was weakest in addressing the European literature, where results about ultrasonography are more prevalent. We found, however, that many of the seminal articles were republished in English or in a form that we could assess.

B. Specific Issues

1. Evidence Quality

Our measure of evidence quality is unique, although it is based on solid principles of study design and decision modeling. In particular, our measure was based on the notion that if the data conform poorly to how we need to use it, we downgrade its value.

However, throughout the analyses, there was never a correlation with the results of a study (in terms of the values of outcomes) and with evidence quality, so we never needed to use the measure for weighting the values of the outcome or for culling articles from our review. Had this been so, the measures would have needed further scrutiny and validation.

2. Outliers

Perhaps the true surrogates for study quality were the outlying values of outcomes. In general, however, there were few cases in which the outliers were clearly the result of poor-quality studies. One example is that of the outcomes of pediatric screening (183), in which the DDH rates in studies using only 2 categories were generally higher than those that explicitly specified 3 levels of outcomes.

Our general justification for using estimates that excluded outliers is that the outliers so much drove the results that they dominated the conclusion out of proportion to their sample sizes. As it is, our estimates have wide ranges.

3. Newborn Screening

The set of studies labeled “pediatrician screening” includes studies with a variety of examiners. We could not estimate the sensitivity and specificity of pediatricians’ examinations versus those of other primary care providers versus orthopaedists. There are techniques for extracting these measures from agreement studies, but they are beyond the scope of the present study. It is intuitive that the more cases that one examines, the better an examiner one will be, regardless of professional title.

We were surprised that the results did not show a clear difference in results between the Graf and Harcke et al ultrasonographic examinations. Our data make no statement about the relative advantages of these methods for following up children or in addressing treatment.

4. Postneonatal Cases

As mentioned, our data cannot say when a postneonatal case is established or, therefore, the best time to screen children. We established our initial age categories for postneonatal cases based on biology, treatment changes, and optimal imaging and examination strategies. It is frustrating that the data in the literature are not organized to match this pathophysiological way of thinking about DDH. Similarly,

as mentioned, the lack of details by authors on the methods of intercurrent screening means that we cannot recommend a preferred method for mid-term or late-term screening.

5. AVN

We used AVN as our primary marker for treatment morbidity. We acknowledge that the studies we grouped together may reflect different philosophies and results of orthopaedic practice. The hierarchical meta-analysis treats every study as an individual case, and the wide range in our confidence intervals reflects the uncertainty that results in grouping disparate studies together.

C. Comments on Methods

This study is unique in its strong use of decision modeling at each step in the process. In the end, our results are couched in traditional terms (estimated rates of disease or morbidity outcomes), although the context is relatively nontraditional: attaching the estimates to strategies rather than to treatments. In this, our study is typical of an *effectiveness* study, which studied results in the real world, rather than of an *efficacy* study, which examines the biological effects of a treatment.

We made strong and recurrent use of the Bayesian hierarchical meta-analysis. A review of the tables will confirm that the Bayesian results were in the same “ballpark” as the average and pooled average estimates and had a more solid grounding.

The usual criticism of using Bayesian methods is that they depend on prior belief. The usual response is to show that the final estimates are relatively insensitive to the prior

belief. In fact, for the screening strategies, a wide range of prior beliefs had no effect on the estimate. However, the prior belief used for the screening strategies—with a mean of 100 cases/1000 with a variance of 100—was too broad for the postneonatal case and AVN analyses; when data were sparse, the prior belief overwhelmed the data. For instance, in late-term DDH revealed by orthopaedic screening (53 30), in an analysis not shown, the posterior estimate from the 4 studies was a rate of 0.345 cases per 1000, despite an average and a pooled average on the order of 0.08. Four studies were insufficient to overpower a prior belief of 100.

D. Research Issues

The place of ultrasonography in DDH screening needs more attention, as does the issue of intercurrent pediatric screening. In the latter case, society and health care systems must assess the effectiveness of education and the “return on investment” for educational programs. The place of preferences—of the parents, of the clinician—must be established.

We hope that the framework we have delineated—of a decision model and of data—can be useful in these future research endeavors.

Dysplasia of the Hip Clinical Practice Guideline

Quick Reference Tools

- Recommendation Summary
 - Early Detection of Developmental Dysplasia of the Hip
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Dysplasia of the Hip
- AAP Patient Education Handout
 - *Hip Dysplasia (Developmental Dysplasia of the Hip)*

Recommendation Summary

Early Detection of Developmental Dysplasia of the Hip

Recommendation 1

- A. All newborns are to be screened by physical examination. (The evidence for this recommendation is good. The expert consensus is strong.)
- B. It is recommended that screening be done by a properly trained health care provider (eg, physician, pediatric nurse practitioner, physician assistant, or physical therapist). (Evidence for this recommendation is strong.)
- C. Ultrasonography of all newborns is not recommended. (Evidence is fair; consensus is strong.)

Recommendation 2

- A. If a positive Ortolani or Barlow sign is found in the newborn examination, the infant should be referred to an orthopaedist. (The data recommending that all those with a positive Ortolani sign be referred to an orthopaedist are limited, but expert panel consensus, nevertheless, was strong....)
- B. If the results of the physical examination at birth are “equivocally” positive (ie, soft click, mild asymmetry, but neither an Ortolani nor a Barlow sign is present), then a follow-up hip examination by the pediatrician in 2 weeks is recommended. (Evidence is good; consensus is strong.)

Recommendation 3

- A. If the results of the newborn physical examination are positive (ie, presence of an Ortolani or a Barlow sign), ordering an ultrasonographic examination of the newborn is not recommended. (Evidence is poor; opinion is strong.)
- B. If the results of the newborn physical examination are positive, obtaining a radiograph of the newborn’s pelvis and hips is not recommended. (Evidence is poor; opinion is strong.)
- C. The use of triple diapers when abnormal physical signs are detected during the newborn period is not recommended. (Evidence is poor; opinion is strong.)

Recommendation 4

If the results of the physical examination are positive (eg, positive Ortolani or Barlow sign) at 2 weeks, refer to an orthopaedist. (Evidence is strong; consensus is strong.)

Recommendation 5

If at the 2-week examination the Ortolani and Barlow signs are absent but physical findings raise suspicions, consider referral to an orthopaedist or request ultrasonography at age 3 to 4 weeks.

Recommendation 6

If the results of the physical examination are negative at 2 weeks, follow-up is recommended at the scheduled well-baby periodic examinations. (Evidence is good; consensus is strong.)

Recommendation 7

Risk factors. If the results of the newborn examination are negative (or equivocally positive), risk factors may be considered. The following recommendations are made (evidence is strong; opinion is strong):

- A. Girl (newborn risk of 19/1000). When the results of the newborn examination are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age.
- B. Infants with a positive family history of DDH (newborn risk for boys of 9.4/1000 and for girls, 44/1000). When the results of the newborn examination in boys are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age. In girls, the absolute risk of 44/1000 may exceed the pediatrician’s threshold to act, and imaging with an ultrasonographic examination at 6 weeks of age or a radiograph of the pelvis at 4 months of age is recommended.
- C. Breech presentation (newborn risk for boys of 26/1000 and for girls, 120/1000). For negative or equivocally positive newborn examinations, the infant should be reevaluated at regular intervals (according to the periodicity schedule) if the examination results remain negative.

Recommendation 8

Periodicity. The hips must be examined at every well-baby visit according to the recommended periodicity schedule for well-baby examinations (2–4 days for newborns discharged in less than 48 hours after delivery, by 1 month, 2 months, 4 months, 6 months, 9 months, and 12 months of age).

Coding Quick Reference for Dysplasia of the Hip	
<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
755.63 Dysplasia, hip, congenital	Q65.89 Other specified congenital deformities of hip Q65.0- Congenital dislocation of hip, unilateral Q65.1 Congenital dislocation of hip, bilateral Q65.2 Congenital dislocation of hip, unspecified Q65.3- Congenital partial dislocation of hip, unilateral Q65.4 Congenital partial dislocation of hip, bilateral Q65.5 Congenital partial dislocation of hip, unspecified Q65.6 Congenital unstable hip (Congenital dislocatable hip)

ICD-10-CM Symbol: “-” Requires a fifth character; 1 = right; 2 = left

Hip Dysplasia

(Developmental Dysplasia of the Hip)



Hip dysplasia (developmental dysplasia of the hip) is a condition in which a child's upper thighbone is dislocated from the hip socket. It can be present at birth or develop during a child's first year of life.

Hip dysplasia is not always detectable at birth or even during early infancy. In spite of careful screening of children for hip dysplasia during regular well-child exams, a number of children with hip dysplasia are not diagnosed until after they are 1 year old.

Hip dysplasia is rare. However, if your baby is diagnosed with the condition, quick treatment is important.

What causes hip dysplasia?

No one is sure why hip dysplasia occurs (or why the left hip dislocates more often than the right hip). One reason may have to do with the hormones a baby is exposed to before birth. While these hormones serve to relax muscles in the pregnant mother's body, in some cases they also may cause a baby's joints to become too relaxed and prone to dislocation. This condition often corrects itself in several days, and the hip develops normally. In some cases, these dislocations cause changes in the hip anatomy that need treatment.

Who is at risk?

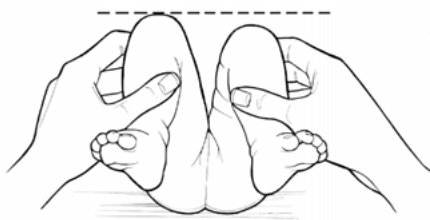
Factors that may increase the risk of hip dysplasia include

- Sex—more frequent in girls
- Family history—more likely when other family members have had hip dysplasia
- Birth position—more common in infants born in the breech position
- Birth order—firstborn children most at risk for hip dysplasia

Detecting hip dysplasia

Your pediatrician will check your newborn for hip dysplasia right after birth and at every well-child exam until your child is walking normally.

During the exam, your child's pediatrician will carefully flex and rotate your child's legs to see if the thighbones are properly positioned in the hip sockets. This does not require a great deal of force and will not hurt your baby.



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Your child's pediatrician also will look for other signs that may suggest a problem, including

- Limited range of motion in either leg
- One leg is shorter than the other
- Thigh or buttock creases appear uneven or lopsided

If your child's pediatrician suspects a problem with your child's hip, you may be referred to an orthopedic specialist who has experience treating hip dysplasia.

Treating hip dysplasia

Early treatment is important. The sooner treatment begins, the simpler it will be. In the past parents were told to double or triple diaper their babies to keep the legs in a position where dislocation was unlikely. *This practice is not recommended.* The diapering will not prevent hip dysplasia and will only delay effective treatment. Failure to treat this condition can result in permanent disability.

If your child is diagnosed with hip dysplasia before she is 6 months old, she will most likely be treated with a soft brace (such as the Pavlik harness) that holds the legs flexed and apart to allow the thighbones to be secure in the hip sockets.

The orthopedic consultant will tell you how long and when your baby will need to wear the brace. Your child also will be examined frequently during this time to make sure that the hips remain normal and stable.

In resistant cases or in older children, hip dysplasia may need to be treated with a combination of braces, casts, traction, or surgery. Your child will be admitted to the hospital if surgery is necessary. After surgery, your child will be placed in a hip spica cast for about 3 months. A hip spica cast is a hard cast that immobilizes the hips and keeps them in the correct position. When the cast is removed, your child will need to wear a removable hip brace for several more months.



Pavlik Harness

Remember

If you have any concerns about your child's walking, talk with his pediatrician. If the cause is hip dysplasia, prompt treatment is important.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

-
- *Clinical Practice Guideline*

CLINICAL PRACTICE GUIDELINE

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

Steering Committee on Quality Improvement and Management, Subcommittee on Febrile Seizures

ABSTRACT

Febrile seizures are the most common seizure disorder in childhood, affecting 2% to 5% of children between the ages of 6 and 60 months. Simple febrile seizures are defined as brief (<15-minute) generalized seizures that occur once during a 24-hour period in a febrile child who does not have an intracranial infection, metabolic disturbance, or history of afebrile seizures. This guideline (a revision of the 1999 American Academy of Pediatrics practice parameter [now termed clinical practice guideline] "The Long-term Treatment of the Child With Simple Febrile Seizures") addresses the risks and benefits of both continuous and intermittent anticonvulsant therapy as well as the use of antipyretics in children with simple febrile seizures. It is designed to assist pediatricians by providing an analytic framework for decisions regarding possible therapeutic interventions in this patient population. It is not intended to replace clinical judgment or to establish a protocol for all patients with this disorder. Rarely will these guidelines be the only approach to this problem. *Pediatrics* 2008;121:1281–1286

The expected outcomes of this practice guideline include:

1. optimizing practitioner understanding of the scientific basis for using or avoiding various proposed treatments for children with simple febrile seizures;
2. improving the health of children with simple febrile seizures by avoiding therapies with high potential for adverse effects and no demonstrated ability to improve children's long-term outcomes;
3. reducing costs by avoiding therapies that will not demonstrably improve children's long-term outcomes; and
4. helping the practitioner educate caregivers about the low risks associated with simple febrile seizures.

The committee determined that with the exception of a high rate of recurrence, no long-term effects of simple febrile seizures have been identified. The risk of developing epilepsy in these patients is extremely low, although slightly higher than that in the general population. No data, however, suggest that prophylactic treatment of children with simple febrile seizures would reduce the risk, because epilepsy likely is the result of genetic predisposition rather than structural damage to the brain caused by recurrent simple febrile seizures. Although antipyretics have been shown to be ineffective in preventing recurrent febrile seizures, there is evidence that continuous anticonvulsant therapy with phenobarbital, primidone, or valproic acid and intermittent therapy with diazepam are effective in reducing febrile-seizure recurrence. The potential toxicities associated with these agents, however, outweigh the relatively minor risks associated with simple febrile seizures. As such, the committee concluded that, on the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

INTRODUCTION

Febrile seizures are seizures that occur in febrile children between the ages of 6 and 60 months who do not have an intracranial infection, metabolic disturbance, or history of afebrile seizures. Febrile seizures are subdivided into 2 categories: simple and complex. Simple febrile seizures last for less than 15 minutes, are generalized (without a focal component), and occur once in a 24-hour period, whereas complex febrile seizures are prolonged (>15 minutes), are focal, or occur more than once in 24 hours.¹ Despite the frequency of febrile seizures (2%–5%), there is no unanimity of opinion about management options. This clinical practice guideline addresses potential therapeutic interventions in neurologically normal children with simple febrile seizures. It is not intended for patients with complex febrile seizures and does not pertain to children with previous neurologic insults, known central nervous system abnor-

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All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Key Word

fever

Abbreviation

AAP—American Academy of Pediatrics

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malities, or a history of afebrile seizures. This clinical practice guideline is a revision of a 1999 American Academy of Pediatrics (AAP) clinical practice parameter, "The Long-term Treatment of the Child With Simple Febrile Seizures."²

For a child who has experienced a simple febrile seizure, there are potentially 4 adverse outcomes that theoretically may be altered by an effective therapeutic agent: (1) decline in IQ; (2) increased risk of epilepsy; (3) risk of recurrent febrile seizures; and (4) death. Neither a decline in IQ, academic performance or neurocognitive inattention nor behavioral abnormalities have been shown to be a consequence of recurrent simple febrile seizures.³ Ellenberg and Nelson⁴ studied 431 children who experienced febrile seizures and observed no significant difference in their learning compared with sibling controls. In a similar study by Verity et al,⁵ 303 children with febrile seizures were compared with control children. No difference in learning was identified, except in those children who had neurologic abnormalities before their first seizure.

The second concern, increased risk of epilepsy, is more complex. Children with simple febrile seizures have approximately the same risk of developing epilepsy by the age of 7 years as does the general population (ie, 1%).⁶ However, children who have had multiple simple febrile seizures, are younger than 12 months at the time of their first febrile seizure, and have a family history of epilepsy are at higher risk, with generalized afebrile seizures developing by 25 years of age in 2.4%.⁷ Despite this fact, no study has demonstrated that successful treatment of simple febrile seizures can prevent this later development of epilepsy, and there currently is no evidence that simple febrile seizures cause structural damage to the brain. Indeed, it is most likely that the increased risk of epilepsy in this population is the result of genetic predisposition.

In contrast to the slightly increased risk of developing epilepsy, children with simple febrile seizures have a high rate of recurrence. The risk varies with age. Children younger than 12 months at the time of their first simple febrile seizure have an approximately 50% probability of having recurrent febrile seizures. Children older than 12 months at the time of their first event have an approximately 30% probability of a second febrile seizure; of those who do have a second febrile seizure, 50% have a chance of having at least 1 additional recurrence.⁸

Finally, there is a theoretical risk of a child dying during a simple febrile seizure as a result of documented injury, aspiration, or cardiac arrhythmia, but to the committee's knowledge, it has never been reported.

In summary, with the exception of a high rate of recurrence, no long-term adverse effects of simple febrile seizures have been identified. Because the risks associated with simple febrile seizures, other than recurrence, are so low and because the number of children who have febrile seizures in the first few years of life is so high, to be commensurate, a proposed therapy would need to be exceedingly low in risks and adverse effects, inexpensive, and highly effective.

METHODS

To update the clinical practice guideline on the treatment of children with simple febrile seizures, the AAP reconvened the Subcommittee on Febrile Seizures. The committee was chaired by a child neurologist and consisted of a neuroepidemiologist, 2 additional child neurologists, and a practicing pediatrician. All panel members reviewed and signed the AAP voluntary disclosure and conflict-of-interest form. The guideline was reviewed by members of the AAP Steering Committee on Quality Improvement and Management; members of the AAP Sections on Neurology, Pediatric Emergency Medicine, Developmental and Behavioral Pediatrics, and Epidemiology; members of the AAP Committees on Pediatric Emergency Medicine and Medical Liability and Risk Management; members of the AAP Councils on Children With Disabilities and Community Pediatrics; and members of outside organizations including the Child Neurology Society and the American Academy of Neurology.

A comprehensive review of the evidence-based literature published since 1998 was conducted with the aim of addressing possible therapeutic interventions in the management of children with simple febrile seizures. The review focused on both the efficacy and potential adverse effects of the proposed treatments. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations.

The AAP established a partnership with the University of Kentucky (Lexington, KY) to develop an evidence report, which served as a major source of information for these practice-guideline recommendations. The specific issues addressed were (1) effectiveness of continuous anticonvulsant therapy in preventing recurrent febrile seizures, (2) effectiveness of intermittent anticonvulsant therapy in preventing recurrent febrile seizures, (3) effectiveness of antipyretics in preventing recurrent febrile seizures, and (4) adverse effects of either continuous or intermittent anticonvulsant therapy.

In the original practice parameter, more than 300 medical journal articles reporting studies of the natural history of simple febrile seizures or the therapy of these seizures were reviewed and abstracted.² An additional 65 articles were reviewed and abstracted for the update. Emphasis was placed on articles that differentiated simple febrile seizures from other types of seizures, that carefully matched treatment and control groups, and that described adherence to the drug regimen. Tables were constructed from the 65 articles that best fit these criteria. A more comprehensive review of the literature on which this report is based can be found in a forthcoming technical report (the initial technical report can be accessed at <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;103/6/e86>). The technical report also will contain dosing information.

The evidence-based approach to guideline development requires that the evidence in support of a recommendation be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs or diagnostic studies on relevant populations	Strong Recommendation	
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation	Option
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations which validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation	

FIGURE 1

Integrating evidence-quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is conducted leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT indicates randomized, controlled trial.

anticipated when the recommendation is followed. The AAP policy statement “Classifying Recommendations for Clinical Practice Guidelines”⁹ was followed in designating levels of recommendations (see Fig 1 and Table 1).

RECOMMENDATION

On the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

- Aggregate evidence quality: B (randomized, controlled trials and diagnostic studies with minor limitations).

- Benefit: prevention of recurrent febrile seizures, which are not harmful and do not significantly increase the risk for development of future epilepsy.
- Harm: adverse effects including rare fatal hepatotoxicity (especially in children younger than 2 years who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis with valproic acid and hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions with phenobarbital; lethargy, drowsiness, and ataxia for intermittent diazepam as well as the risk of masking an evolving central nervous system infection.
- Benefits/harms assessment: preponderance of harm over benefit.
- Policy level: recommendation.

BENEFITS AND RISKS OF CONTINUOUS ANTICONVULSANT THERAPY

Phenobarbital

Phenobarbital is effective in preventing the recurrence of simple febrile seizures.¹⁰ In a controlled double-blind study, daily therapy with phenobarbital reduced the rate of subsequent febrile seizures from 25 per 100 subjects per year to 5 per 100 subjects per year.¹¹ For the agent to be effective, however, it must be given daily and maintained in the therapeutic range. In a study by Farwell et al,¹² for example, children whose phenobarbital levels were in the therapeutic range had a reduction in recurrent seizures, but because noncompliance was so high, an overall benefit with phenobarbital therapy was not identified.

The adverse effects of phenobarbital include hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions. The behavioral adverse effects

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

may occur in up to 20% to 40% of patients and may be severe enough to necessitate discontinuation of the drug.^{13–16}

Primidone

Primidone, in doses of 15 to 20 mg/kg per day, has also been shown to reduce the recurrence rate of febrile seizures.^{17,18} It is of interest that the derived phenobarbital level in a Minigawa and Miura study¹⁷ was below therapeutic (16 $\mu\text{g/mL}$) in 29 of the 32 children, suggesting that primidone itself may be active in preventing seizure recurrence. As with phenobarbital, adverse effects include behavioral disturbances, irritability, and sleep disturbances.¹⁸

Valproic Acid

In randomized, controlled studies, only 4% of children taking valproic acid, as opposed to 35% of control subjects, had a subsequent febrile seizure. Therefore, valproic acid seems to be at least as effective in preventing recurrent simple febrile seizures as phenobarbital and significantly more effective than placebo.^{19–21}

Drawbacks to therapy with valproic acid include its rare association with fatal hepatotoxicity (especially in children younger than 2 years, who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis. In studies in which children received valproic acid to prevent recurrence of febrile seizures, no cases of fatal hepatotoxicity were reported.¹⁵

Carbamazepine

Carbamazepine has not been shown to be effective in preventing the recurrence of simple febrile seizures. Antony and Hawke¹³ compared children who had been treated with therapeutic levels of either phenobarbital or carbamazepine, and 47% of the children in the carbamazepine-treated group had recurrent seizures compared with only 10% of those in the phenobarbital group. In another study, Camfield et al²² treated children (whose conditions failed to improve with phenobarbital therapy) with carbamazepine. Despite good compliance, 13 of the 16 children treated with carbamazepine had a recurrent febrile seizure within 18 months. It is theoretically possible that these excessively high rates of recurrences might have been attributable to adverse effects of carbamazepine.

Phenytoin

Phenytoin has not been shown to be effective in preventing the recurrence of simple febrile seizures, even when the agent is in the therapeutic range.^{23,24} Other anticonvulsants have not been studied for the continuous treatment of simple febrile seizures.

BENEFITS AND RISKS OF INTERMITTENT ANTICONVULSANT THERAPY

Diazepam

A double-blind controlled study of patients with a history of febrile seizures demonstrated that administration

of oral diazepam (given at the time of fever) could reduce the recurrence of febrile seizures. Children with a history of febrile seizures were given either oral diazepam (0.33 mg/kg, every 8 hours for 48 hours) or a placebo at the time of fever. The risk of febrile seizures per person-year was decreased 44% with diazepam.²⁵ In a more recent study, children with a history of febrile seizures were given oral diazepam at the time of fever and then compared with children in an untreated control group. In the oral diazepam group, there was an 11% recurrence rate compared with a 30% recurrence rate in the control group.²⁶ It should be noted that all children for whom diazepam was considered a failure had been noncompliant with drug administration, in part because of adverse effects of the medication.

There is also literature that demonstrates the feasibility and safety of interrupting a simple febrile seizure lasting less than 5 minutes with rectal diazepam and with both intranasal and buccal midazolam.^{27,28} Although these agents are effective in terminating the seizure, it is questionable whether they have any long-term influence on outcome. In a study by Knudsen et al,²⁹ children were given either rectal diazepam at the time of fever or only at the onset of seizure. Twelve-year follow-up found that the long-term prognosis of the children in the 2 groups did not differ regardless of whether treatment was aimed at preventing seizures or treating them.

A potential drawback to intermittent medication is that a seizure could occur before a fever is noticed. Indeed, in several of these studies, recurrent seizures were likely attributable to failure of method rather than failure of the agent.

Adverse effects of oral and rectal diazepam²⁶ and both intranasal and buccal midazolam include lethargy, drowsiness, and ataxia. Respiratory depression is extremely rare, even when given by the rectal route.^{28,30} Sedation caused by any of the benzodiazepines, whether administered by the oral, rectal, nasal, or buccal route, have the potential of masking an evolving central nervous system infection. If used, the child's health care professional should be contacted.

BENEFITS AND RISKS OF INTERMITTENT ANTIPYRETICS

No studies have demonstrated that antipyretics, in the absence of anticonvulsants, reduce the recurrence risk of simple febrile seizures. Camfield et al¹¹ treated 79 children who had had a first febrile seizure with either a placebo plus antipyretic instruction (either aspirin or acetaminophen) versus daily phenobarbital plus antipyretic instruction (either aspirin or acetaminophen). Recurrence risk was significantly lower in the phenobarbital-treated group, suggesting that antipyretic instruction, including the use of antipyretics, is ineffective in preventing febrile-seizure recurrence.

Whether antipyretics are given regularly (every 4 hours) or sporadically (contingent on a specific body-temperature elevation) does not influence outcome. Acetaminophen was either given every 4 hours or only for temperature elevations of more than 37.9°C in 104 children. The incidence of febrile episodes did not differ

significantly between the 2 groups, nor did the early recurrence of febrile seizures. The authors determined that administering prophylactic acetaminophen during febrile episodes was ineffective in preventing or reducing fever and in preventing febrile-seizure recurrence.³¹

In a randomized double-blind placebo-controlled trial, acetaminophen was administered along with low-dose oral diazepam.³² Febrile-seizure recurrence was not reduced, compared with control groups. As with acetaminophen, ibuprofen also has been shown to be ineffective in preventing recurrence of febrile seizures.^{33–35}

In general, acetaminophen and ibuprofen are considered to be safe and effective antipyretics for children. However, hepatotoxicity (with acetaminophen) and respiratory failure, metabolic acidosis, renal failure, and coma (with ibuprofen) have been reported in children after overdose or in the presence of risk factors.^{36,37}

CONCLUSIONS

The subcommittee has determined that a simple febrile seizure is a benign and common event in children between the ages of 6 and 60 months. Nearly all children have an excellent prognosis. The committee concluded that although there is evidence that both continuous antiepileptic therapy with phenobarbital, primidone, or valproic acid and intermittent therapy with oral diazepam are effective in reducing the risk of recurrence, the potential toxicities associated with antiepileptic drugs outweigh the relatively minor risks associated with simple febrile seizures. As such, long-term therapy is not recommended. In situations in which parental anxiety associated with febrile seizures is severe, intermittent oral diazepam at the onset of febrile illness may be effective in preventing recurrence. Although antipyretics may improve the comfort of the child, they will not prevent febrile seizures.

SUBCOMMITTEE ON FEBRILE SEIZURES, 2002–2008

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Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

-
- *Clinical Practice Guideline*

Clinical Practice Guideline—Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

SUBCOMMITTEE ON FEBRILE SEIZURES

KEY WORD

seizure

ABBREVIATIONS

AAP—American Academy of Pediatrics

Hib—*Haemophilus influenzae* type b

EEG—electroencephalogram

CT—computed tomography

The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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OBJECTIVE: To formulate evidence-based recommendations for health care professionals about the diagnosis and evaluation of a simple febrile seizure in infants and young children 6 through 60 months of age and to revise the practice guideline published by the American Academy of Pediatrics (AAP) in 1996.

METHODS: This review included search and analysis of the medical literature published since the last version of the guideline. Physicians with expertise and experience in the fields of neurology and epilepsy, pediatrics, epidemiology, and research methodologies constituted a subcommittee of the AAP Steering Committee on Quality Improvement and Management. The steering committee and other groups within the AAP and organizations outside the AAP reviewed the guideline. The subcommittee member who reviewed the literature for the 1996 AAP practice guidelines searched for articles published since the last guideline through 2009, supplemented by articles submitted by other committee members. Results from the literature search were provided to the subcommittee members for review. Interventions of direct interest included lumbar puncture, electroencephalography, blood studies, and neuroimaging. Multiple issues were raised and discussed iteratively until consensus was reached about recommendations. The strength of evidence supporting each recommendation and the strength of the recommendation were assessed by the committee member most experienced in informatics and epidemiology and graded according to AAP policy.

CONCLUSIONS: Clinicians evaluating infants or young children after a simple febrile seizure should direct their attention toward identifying the cause of the child's fever. Meningitis should be considered in the differential diagnosis for any febrile child, and lumbar puncture should be performed if there are clinical signs or symptoms of concern. For any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended), or when immunization status cannot be determined, because of an increased risk of bacterial meningitis. A lumbar puncture is an option for children who are pretreated with antibiotics. In general, a simple febrile seizure does not usually require further evaluation, specifically electroencephalography, blood studies, or neuroimaging. *Pediatrics* 2011;127:389–394

DEFINITION OF THE PROBLEM

This practice guideline provides recommendations for the neurodiagnostic evaluation of neurologically healthy infants and children 6 through 60 months of age who have had a simple febrile seizure and present for evaluation within 12 hours of the event. It replaces the 1996 practice parameter.¹ This practice guideline is not intended for patients who have had complex febrile seizures (prolonged, focal, and/or recurrent), and it does not pertain to children with previous neurologic insults, known central nervous system abnormalities, or history of afebrile seizures.

TARGET AUDIENCE AND PRACTICE SETTING

This practice guideline is intended for use by pediatricians, family physicians, child neurologists, neurologists, emergency physicians, nurse practitioners, and other health care providers who evaluate children for febrile seizures.

BACKGROUND

A febrile seizure is a seizure accompanied by fever (temperature $\geq 100.4^{\circ}\text{F}$ or 38°C ² by any method), without central nervous system infection, that occurs in infants and children 6 through 60 months of age. Febrile seizures occur in 2% to 5% of all children and, as such, make up the most common convulsive event in children younger than 60 months. In 1976, Nelson and Ellenberg,³ using data from the National Collaborative Perinatal Project, further defined febrile seizures as being either simple or complex. Simple febrile seizures were defined as primary generalized seizures that lasted for less than 15 minutes and did not recur within 24 hours. Complex febrile seizures were defined as focal, prolonged (≥ 15 minutes), and/or recurrent within 24 hours. Children who had simple febrile seizures had no evidence of increased mortality, hemiplegia, or mental retardation. During follow-up evaluation, the risk of epilepsy after a

simple febrile seizure was shown to be only slightly higher than that of the general population, whereas the chief risk associated with simple febrile seizures was recurrence in one-third of the children. The authors concluded that simple febrile seizures are benign events with excellent prognoses, a conclusion reaffirmed in the 1980 consensus statement from the National Institutes of Health.^{3,4}

The expected outcomes of this practice guideline include the following:

1. Optimize clinician understanding of the scientific basis for the neurodiagnostic evaluation of children with simple febrile seizures.
2. Aid the clinician in decision-making by using a structured framework.
3. Optimize evaluation of the child who has had a simple febrile seizure by detecting underlying diseases, minimizing morbidity, and reassuring anxious parents and children.
4. Reduce the costs of physician and emergency department visits, hospitalizations, and unnecessary testing.
5. Educate the clinician to understand that a simple febrile seizure usually does not require further evaluation, specifically electroencephalography, blood studies, or neuroimaging.

METHODOLOGY

To update the clinical practice guideline on the neurodiagnostic evaluation of children with simple febrile seizures,¹ the American Academy of Pediatrics (AAP) reconvened the Subcommittee on Febrile Seizures. The committee was chaired by a child neurologist and consisted of a neuroepidemiologist, 3 additional child neurologists, and a practicing pediatrician. All panel members reviewed and signed the AAP voluntary disclosure and conflict-of-interest form. No conflicts were reported. Participation in the guideline process was voluntary and not paid. The guideline was reviewed by members of the AAP Steering Commit-

tee on Quality Improvement and Management; members of the AAP Section on Administration and Practice Management, Section on Developmental and Behavioral Pediatrics, Section on Epidemiology, Section on Infectious Diseases, Section on Neurology, Section on Neurologic Surgery, Section on Pediatric Emergency Medicine, Committee on Pediatric Emergency Medicine, Committee on Practice and Ambulatory Medicine, Committee on Child Health Financing, Committee on Infectious Diseases, Committee on Medical Liability and Risk Management, Council on Children With Disabilities, and Council on Community Pediatrics; and members of outside organizations including the Child Neurology Society, the American Academy of Neurology, the American College of Emergency Physicians, and members of the Pediatric Committee of the Emergency Nurses Association.

A comprehensive review of the evidence-based literature published from 1996 to February 2009 was conducted to discover articles that addressed the diagnosis and evaluation of children with simple febrile seizures. Preference was given to population-based studies, but given the scarcity of such studies, data from hospital-based studies, groups of young children with febrile illness, and comparable groups were reviewed. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations.

In the original practice parameter,¹ 203 medical journal articles were reviewed and abstracted. An additional 372 articles were reviewed and abstracted for this update. Emphasis was placed on articles that differentiated simple febrile seizures from other types of seizures. Tables were constructed from the 70 articles that best fit these criteria.

The evidence-based approach to guideline development requires that the evidence in support of a recommendation be identified, appraised, and summarized and that an explicit link between

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCT or diagnostic studies on relevant population	Strong	Option
B. RCT or diagnostic studies with limitations, overwhelmingly consistent evidence from observational studies	Rec	
C. Observational studies (case-control and cohort studies)	Option	No Rec
D. Expert opinion, case reports, reasoning from first principles	Strong	Rec
E. Exceptional situations in which a strong and consistent evidence base indicates a clear preponderance of benefit or harm	Rec	

FIGURE 1

Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT indicates randomized controlled trial; Rec, recommendation.

evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement “Classifying Recommendations for Clinical Practice Guidelines”⁵ was followed in designating levels of recommendations (see Fig 1).

KEY ACTION STATEMENTS

Action Statement 1

Action Statement 1a

A lumbar puncture should be performed in any child who presents with a seizure and a fever and has meningeal signs and symptoms (eg, neck stiffness, Kernig and/or Brudzinski signs) or in any child whose history or examination suggests the presence of meningitis or intracranial infection.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: Meningeal signs and symptoms strongly suggest meningitis, which, if bacterial in etiology, will likely be fatal if left untreated.
- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.

- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Observational data and clinical principles were used in making this judgment.
- Role of patient preferences: Although parents may not wish to have their child undergo a lumbar puncture, health care providers should explain that if meningitis is not diagnosed and treated, it could be fatal.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

Action Statement 1b

In any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended) or when immunization status cannot be determined because of an increased risk of bacterial meningitis.

- Aggregate evidence level: D (expert opinion, case reports).
- Benefits: Meningeal signs and symptoms strongly suggest meningitis, which, if bacterial in etiology, will

likely be fatal or cause significant long-term disability if left untreated.

- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.
- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Data on the incidence of bacterial meningitis from before and after the existence of immunizations against Hib and *S pneumoniae* were used in making this recommendation.
- Role of patient preferences: Although parents may not wish their child to undergo a lumbar puncture, health care providers should explain that in the absence of complete immunizations, their child may be at risk of having fatal bacterial meningitis.
- Exclusions: This recommendation applies only to children 6 to 12 months of age. The subcommittee felt that clinicians would recognize symptoms of meningitis in children older than 12 months.
- Intentional vagueness: None.
- Policy level: Option.

Action Statement 1c

A lumbar puncture is an option in the child who presents with a seizure and fever and is pretreated with antibiotics, because antibiotic treatment can mask the signs and symptoms of meningitis.

- Aggregate evidence level: D (reasoning from clinical experience, case series).
- Benefits: Antibiotics may mask meningeal signs and symptoms but may be insufficient to eradicate meningitis; a diagnosis of meningitis, if bacterial in etiology, will likely be fatal if left untreated.
- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.

- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Clinical experience and case series were used in making this judgment while recognizing that extensive data from studies are lacking.
- Role of patient preferences: Although parents may not wish to have their child undergo a lumbar puncture, medical providers should explain that in the presence of pretreatment with antibiotics, the signs and symptoms of meningitis may be masked. Meningitis, if untreated, can be fatal.
- Exclusions: None.
- Intentional vagueness: Data are insufficient to define the specific treatment duration necessary to mask signs and symptoms. The committee determined that the decision to perform a lumbar puncture will depend on the type and duration of antibiotics administered before the seizure and should be left to the individual clinician.
- Policy level: Option.

The committee recognizes the diversity of past and present opinions regarding the need for lumbar punctures in children younger than 12 months with a simple febrile seizure. Since the publication of the previous practice parameter,¹ however, there has been widespread immunization in the United States for 2 of the most common causes of bacterial meningitis in this age range: Hib and *S pneumoniae*. Although compliance with all scheduled immunizations as recommended does not completely eliminate the possibility of bacterial meningitis from the differential diagnosis, current data no longer support routine lumbar puncture in well-appearing, fully immunized children who present with a simple febrile seizure.⁶⁻⁸ Moreover, although approximately 25% of young children with meningitis have seizures as the presenting sign of the disease, some are ei-

ther obtunded or comatose when evaluated by a physician for the seizure, and the remainder most often have obvious clinical signs of meningitis (focal seizures, recurrent seizures, petechial rash, or nuchal rigidity).⁹⁻¹¹ Once a decision has been made to perform a lumbar puncture, then blood culture and serum glucose testing should be performed concurrently to increase the sensitivity for detecting bacteria and to determine if there is hypoglycorrachia characteristic of bacterial meningitis, respectively. Recent studies that evaluated the outcome of children with simple febrile seizures have included populations with a high prevalence of immunization.^{7,8} Data for unimmunized or partially immunized children are lacking. Therefore, lumbar puncture is an option for young children who are considered deficient in immunizations or those in whom immunization status cannot be determined. There are also no definitive data on the outcome of children who present with a simple febrile seizure while already on antibiotics. The authors were unable to find a definition of "pretreated" in the literature, so they consulted with the AAP Committee on Infectious Diseases. Although there is no formal definition, pretreatment can be considered to include systemic antibiotic therapy by any route given within the days before the seizure. Whether pretreatment will affect the presentation and course of bacterial meningitis cannot be predicted but will depend, in part, on the antibiotic administered, the dose, the route of administration, the drug's cerebrospinal fluid penetration, and the organism causing the meningitis. Lumbar puncture is an option in any child pretreated with antibiotics before a simple febrile seizure.

Action Statement 2

An electroencephalogram (EEG) should not be performed in the evaluation of a neurologically healthy child with a simple febrile seizure.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: One study showed a possible association with paroxysmal EEGs and a higher rate of afebrile seizures.¹²
- Harms/risks/costs: EEGs are costly and may increase parental anxiety.
- Benefits/harms assessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although an EEG might have limited prognostic utility in this situation, parents should be educated that the study will not alter outcome.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

There is no evidence that EEG readings performed either at the time of presentation after a simple febrile seizure or within the following month are predictive of either recurrence of febrile seizures or the development of afebrile seizures/epilepsy within the next 2 years.^{13,14} There is a single study that found that a paroxysmal EEG was associated with a higher rate of afebrile seizures.¹² There is no evidence that interventions based on this test would alter outcome.

Action Statement 3

The following tests should not be performed routinely for the sole purpose of identifying the cause of a simple febrile seizure: measurement of serum electrolytes, calcium, phosphorus, magnesium, or blood glucose or complete blood cell count.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: A complete blood cell count may identify children at risk for bacte-

remia; however, the incidence of bacteremia in febrile children younger than 24 months is the same with or without febrile seizures.

- Harms/risks/costs: Laboratory tests may be invasive and costly and provide no real benefit.
- Benefits/harmsassessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although parents may want blood tests performed to explain the seizure, they should be reassured that blood tests should be directed toward identifying the source of their child's fever.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

There is no evidence to suggest that routine blood studies are of benefit in the evaluation of the child with a simple febrile seizure.^{15–18} Although some children with febrile seizures have abnormal serum electrolyte values, their condition should be identifiable by obtaining appropriate histories and performing careful physical examinations. It should be noted that as a group, children with febrile seizures have relatively low serum sodium concentrations. As such, physicians and caregivers should avoid overhydration with hypotonic fluids.¹⁸ Complete blood cell counts may be useful as a means of identifying young children at risk of bacteremia. It should be noted, however, that the incidence of bacteremia in children younger than 24 months with or without febrile seizures is the same. When fever is present, the decision regarding the need for laboratory testing should be directed toward identifying the source of the fever rather

than as part of the routine evaluation of the seizure itself.

Action Statement 4

Neuroimaging should not be performed in the routine evaluation of the child with a simple febrile seizure.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: Neuroimaging might provide earlier detection of fixed structural lesions, such as dysplasia, or very rarely, abscess or tumor.
- Harms/risks/costs: Neuroimaging tests are costly, computed tomography (CT) exposes children to radiation, and MRI may require sedation.
- Benefits/harmsassessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although parents may want neuroimaging performed to explain the seizure, they should be reassured that the tests carry risks and will not alter outcome for their child.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

The literature does not support the use of skull films in evaluation of the child with a febrile seizure.^{15,19} No data have been published that either support or negate the need for CT or MRI in the evaluation of children with simple febrile seizures. Data, however, show that CT scanning is associated with radiation exposure that may escalate future cancer risk. MRI is associated with risks from required sedation and high cost.^{20,21} Extrapolation of data from the

literature on the use of CT in neurologically healthy children who have generalized epilepsy has shown that clinically important intracranial structural abnormalities in this patient population are uncommon.^{22,23}

CONCLUSIONS

Clinicians evaluating infants or young children after a simple febrile seizure should direct their attention toward identifying the cause of the child's fever. Meningitis should be considered in the differential diagnosis for any febrile child, and lumbar puncture should be performed if the child is ill-appearing or if there are clinical signs or symptoms of concern. A lumbar puncture is an option in a child 6 to 12 months of age who is deficient in Hib and *S pneumoniae* immunizations or for whom immunization status is unknown. A lumbar puncture is an option in children who have been pretreated with antibiotics. In general, a simple febrile seizure does not usually require further evaluation, specifically EEGs, blood studies, or neuroimaging.

SUBCOMMITTEE ON FEBRILE SEIZURES, 2002–2010

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OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2009–2011

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Febrile Seizures Clinical Practice Guidelines

Quick Reference Tools

- Recommendation Summaries
 - Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures
 - Febrile Seizures: Guidelines for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Febrile Seizures
- AAP Patient Education Handout
 - *Febrile Seizures*

Recommendation Summaries

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

On the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

- Aggregate evidence quality: B (randomized, controlled trials and diagnostic studies with minor limitations).
- Benefit: prevention of recurrent febrile seizures, which are not harmful and do not significantly increase the risk for development of future epilepsy.
- Harm: adverse effects including rare fatal hepatotoxicity (especially in children younger than 2 years who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis with valproic acid and hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions with phenobarbital; lethargy, drowsiness, and ataxia for intermittent diazepam as well as the risk of masking an evolving central nervous system infection.
- Benefits/harms assessment: preponderance of harm over benefit.
- Policy level: recommendation.

Febrile Seizures: Guidelines for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

Action Statement 1a

A lumbar puncture should be performed in any child who presents with a seizure and a fever and has meningeal signs and symptoms (eg, neck stiffness, Kernig and/or Brudzinski signs) or in any child whose history or exami-

nation suggests the presence of meningitis or intracranial infection.

Action Statement 1b

In any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended) or when immunization status cannot be determined because of an increased risk of bacterial meningitis.

Action Statement 1c

A lumbar puncture is an option in the child who presents with a seizure and fever and is pretreated with antibiotics, because antibiotic treatment can mask the signs and symptoms of meningitis.

Action Statement 2

An electroencephalogram (EEG) should not be performed in the evaluation of a neurologically healthy child with a simple febrile seizure.

Action Statement 3

The following tests should not be performed routinely for the sole purpose of identifying the cause of a simple febrile seizure: measurement of serum electrolytes, calcium, phosphorus, magnesium, or blood glucose or complete blood cell count.

Action Statement 4

Neuroimaging should not be performed in the routine evaluation of the child with a simple febrile seizure.

Coding Quick Reference for Febrile Seizures

ICD-9-CM	ICD-10-CM
780.31 Seizure, febrile, simple	R56.00 Simple febrile convulsions
780.32 Seizure, febrile, complex	R56.01 Complex febrile convulsions

Febrile Seizures



In some children, fevers can trigger seizures. Febrile seizures occur in 2% to 5% of all children between the ages of 6 months and 5 years. Seizures, sometimes called “fits” or “spells,” are frightening, but they usually are harmless. Read on for information from the American Academy of Pediatrics that will help you understand febrile seizures and what happens if your child has one.

What is a febrile seizure?

A febrile seizure usually happens during the first few hours of a fever. The child may look strange for a few moments, then stiffen, twitch, and roll his eyes. He will be unresponsive for a short time, his breathing will be disturbed, and his skin may appear a little darker than usual. After the seizure, the child quickly returns to normal. Seizures usually last less than 1 minute but, although uncommon, can last for up to 15 minutes.

Febrile seizures rarely happen more than once within a 24-hour period. Other kinds of seizures (ones that are not caused by fever) last longer, can affect only one part of the body, and may occur repeatedly.

What do I do if my child has a febrile seizure?

If your child has a febrile seizure, act immediately to prevent injury.

- Place her on the floor or bed away from any hard or sharp objects.
- Turn her head to the side so that any saliva or vomit can drain from her mouth.
- Do not put anything into her mouth; she will not swallow her tongue.
- Call your child's doctor.
- If the seizure does not stop after 5 minutes, call 911 or your local emergency number.

Will my child have more seizures?

Febrile seizures tend to run in families. The risk of having seizures with other episodes of fever depends on the age of your child. Children younger than 1 year of age at the time of their first seizure have about a 50% chance of having another febrile seizure. Children older than 1 year of age at the time of their first seizure have only a 30% chance of having a second febrile seizure.

Will my child get epilepsy?

Epilepsy is a term used for multiple and recurrent seizures. Epileptic seizures are not caused by fever. Children with a history of febrile seizures are at only a slightly higher risk of developing epilepsy by age 7 than children who have not had febrile seizures.

Are febrile seizures dangerous?

While febrile seizures may be very scary, they are harmless to the child. Febrile seizures do not cause brain damage, nervous system problems, paralysis, intellectual disability (formerly called mental retardation), or death.

How are febrile seizures treated?

If your child has a febrile seizure, call your child's doctor right away. He or she will want to examine your child in order to determine the cause of your child's fever. It is more important to determine and treat the cause of the fever rather than the seizure. A spinal tap may be done to be sure your child does not have a serious infection like meningitis, especially if your child is younger than 1 year of age.

In general, doctors do not recommend treatment of a simple febrile seizure with preventive medicines. However, this should be discussed with your child's doctor. In cases of prolonged or repeated seizures, the recommendation may be different.

Medicines like acetaminophen and ibuprofen can help lower a fever, but they do not prevent febrile seizures. Your child's doctor will talk with you about the best ways to take care of your child's fever.

If your child has had a febrile seizure, do not fear the worst. These types of seizures are not dangerous to your child and do not cause long-term health problems. If you have concerns about this issue or anything related to your child's health, talk with your child's doctor.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

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Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

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- *Clinical Practice Guideline*
- *Technical Report Summary*
- *Technical Report*
- *2009 Commentaries*

Readers of this clinical practice guideline are urged to review the technical reports to enhance the evidence-based decision-making process. The full technical reports are available on the companion CD-ROM.

AMERICAN ACADEMY OF PEDIATRICS

CLINICAL PRACTICE GUIDELINE

Subcommittee on Hyperbilirubinemia

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

ABSTRACT. Jaundice occurs in most newborn infants. Most jaundice is benign, but because of the potential toxicity of bilirubin, newborn infants must be monitored to identify those who might develop severe hyperbilirubinemia and, in rare cases, acute bilirubin encephalopathy or kernicterus. The focus of this guideline is to reduce the incidence of severe hyperbilirubinemia and bilirubin encephalopathy while minimizing the risks of unintended harm such as maternal anxiety, decreased breastfeeding, and unnecessary costs or treatment. Although kernicterus should almost always be preventable, cases continue to occur. These guidelines provide a framework for the prevention and management of hyperbilirubinemia in newborn infants of 35 or more weeks of gestation. In every infant, we recommend that clinicians 1) promote and support successful breastfeeding; 2) perform a systematic assessment before discharge for the risk of severe hyperbilirubinemia; 3) provide early and focused follow-up based on the risk assessment; and 4) when indicated, treat newborns with phototherapy or exchange transfusion to prevent the development of severe hyperbilirubinemia and, possibly, bilirubin encephalopathy (kernicterus). *Pediatrics* 2004; 114:297–316; *hyperbilirubinemia, newborn, kernicterus, bilirubin encephalopathy, phototherapy.*

ABBREVIATIONS. AAP, American Academy of Pediatrics; TSB, total serum bilirubin; TcB, transcutaneous bilirubin; G6PD, glucose-6-phosphate dehydrogenase; ETCO₂, end-tidal carbon monoxide corrected for ambient carbon monoxide; B/A, bilirubin/albumin; UB, unbound bilirubin.

BACKGROUND

In October 1994, the Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia of the American Academy of Pediatrics (AAP) produced a practice parameter dealing with the management of hyperbilirubinemia in the healthy term newborn.¹ The current guideline represents a consensus of the committee charged by the AAP with reviewing and updating the existing guideline and is based on a careful review of the evidence, including a comprehensive literature review by the New England Medical Center Evidence-Based Practice Center.² (See "An Evidence-Based Review of Important Issues Concerning Neonatal

Hyperbilirubinemia"³ for a description of the methodology, questions addressed, and conclusions of this report.) This guideline is intended for use by hospitals and pediatricians, neonatologists, family physicians, physician assistants, and advanced practice nurses who treat newborn infants in the hospital and as outpatients. A list of frequently asked questions and answers for parents is available in English and Spanish at www.aap.org/family/jaundicefaq.htm.

DEFINITION OF RECOMMENDATIONS

The evidence-based approach to guideline development requires that the evidence in support of a policy be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations are based on the quality of evidence and the balance of benefits and harms that is anticipated when the recommendation is followed. This guideline uses the definitions for quality of evidence and balance of benefits and harms established by the AAP Steering Committee on Quality Improvement Management.⁴ See Appendix 1 for these definitions.

The draft practice guideline underwent extensive peer review by committees and sections within the AAP, outside organizations, and other individuals identified by the subcommittee as experts in the field. Liaison representatives to the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and, when appropriate, incorporated into the guideline.

BILIRUBIN ENCEPHALOPATHY AND KERNICTERUS

Although originally a pathologic diagnosis characterized by bilirubin staining of the brainstem nuclei and cerebellum, the term "kernicterus" has come to be used interchangeably with both the acute and chronic findings of bilirubin encephalopathy. Bilirubin encephalopathy describes the clinical central nervous system findings caused by bilirubin toxicity to the basal ganglia and various brainstem nuclei. To avoid confusion and encourage greater consistency in the literature, the committee recommends that in infants the term "acute bilirubin encephalopathy" be used to describe the acute manifestations of bilirubin

toxicity seen in the first weeks after birth and that the term “kernicterus” be reserved for the chronic and permanent clinical sequelae of bilirubin toxicity.

See Appendix 1 for the clinical manifestations of acute bilirubin encephalopathy and kernicterus.

FOCUS OF GUIDELINE

The overall aim of this guideline is to promote an approach that will reduce the frequency of severe neonatal hyperbilirubinemia and bilirubin encephalopathy and minimize the risk of unintended harm such as increased anxiety, decreased breastfeeding, or unnecessary treatment for the general population and excessive cost and waste. Recent reports of kernicterus indicate that this condition, although rare, is still occurring.^{2,5–10}

Analysis of these reported cases of kernicterus suggests that if health care personnel follow the recommendations listed in this guideline, kernicterus would be largely preventable.

These guidelines emphasize the importance of universal systematic assessment for the risk of severe hyperbilirubinemia, close follow-up, and prompt intervention when indicated. The recommendations apply to the care of infants at 35 or more weeks of gestation. These recommendations seek to further the aims defined by the Institute of Medicine as appropriate for health care:¹¹ safety, effectiveness, efficiency, timeliness, patient-centeredness, and equity. They specifically emphasize the principles of patient safety and the key role of timeliness of interventions to prevent adverse outcomes resulting from neonatal hyperbilirubinemia.

The following are the key elements of the recommendations provided by this guideline. Clinicians should:

1. Promote and support successful breastfeeding.
2. Establish nursery protocols for the identification and evaluation of hyperbilirubinemia.
3. Measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours.
4. Recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
5. Interpret all bilirubin levels according to the infant's age in hours.
6. Recognize that infants at less than 38 weeks' gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring.
7. Perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia.
8. Provide parents with written and verbal information about newborn jaundice.
9. Provide appropriate follow-up based on the time of discharge and the risk assessment.
10. Treat newborns, when indicated, with phototherapy or exchange transfusion.

PRIMARY PREVENTION

In numerous policy statements, the AAP recommends breastfeeding for all healthy term and near-term newborns. This guideline strongly supports this general recommendation.

RECOMMENDATION 1.0: *Clinicians should advise mothers to nurse their infants at least 8 to 12 times per day for the first several days¹² (evidence quality C: benefits exceed harms).*

Poor caloric intake and/or dehydration associated with inadequate breastfeeding may contribute to the development of hyperbilirubinemia.^{6,13,14} Increasing the frequency of nursing decreases the likelihood of subsequent significant hyperbilirubinemia in breastfed infants.^{15–17} Providing appropriate support and advice to breastfeeding mothers increases the likelihood that breastfeeding will be successful.

Additional information on how to assess the adequacy of intake in a breastfed newborn is provided in Appendix 1.

RECOMMENDATION 1.1: *The AAP recommends against routine supplementation of nondehydrated breastfed infants with water or dextrose water (evidence quality B and C: harms exceed benefits).*

Supplementation with water or dextrose water will not prevent hyperbilirubinemia or decrease TSB levels.^{18,19}

SECONDARY PREVENTION

RECOMMENDATION 2.0: *Clinicians should perform ongoing systematic assessments during the neonatal period for the risk of an infant developing severe hyperbilirubinemia.*

Blood Typing

RECOMMENDATION 2.1: *All pregnant women should be tested for ABO and Rh (D) blood types and have a serum screen for unusual isoimmune antibodies (evidence quality B: benefits exceed harms).*

RECOMMENDATION 2.1.1: *If a mother has not had prenatal blood grouping or is Rh-negative, a direct antibody test (or Coombs' test), blood type, and an Rh (D) type on the infant's (cord) blood are strongly recommended (evidence quality B: benefits exceed harms).*

RECOMMENDATION 2.1.2: *If the maternal blood is group O, Rh-positive, it is an option to test the cord blood for the infant's blood type and direct antibody test, but it is not required provided that there is appropriate surveillance, risk assessment before discharge, and follow-up²⁰ (evidence quality C: benefits exceed harms).*

Clinical Assessment

RECOMMENDATION 2.2: *Clinicians should ensure that all infants are routinely monitored for the development of jaundice, and nurseries should have established protocols for the assessment of jaundice. Jaundice should be assessed whenever the infant's vital signs are measured but no less than every 8 to 12 hours (evidence quality D: benefits versus harms exceptional).*

In newborn infants, jaundice can be detected by blanching the skin with digital pressure, revealing the underlying color of the skin and subcutaneous tissue. The assessment of jaundice must be per-

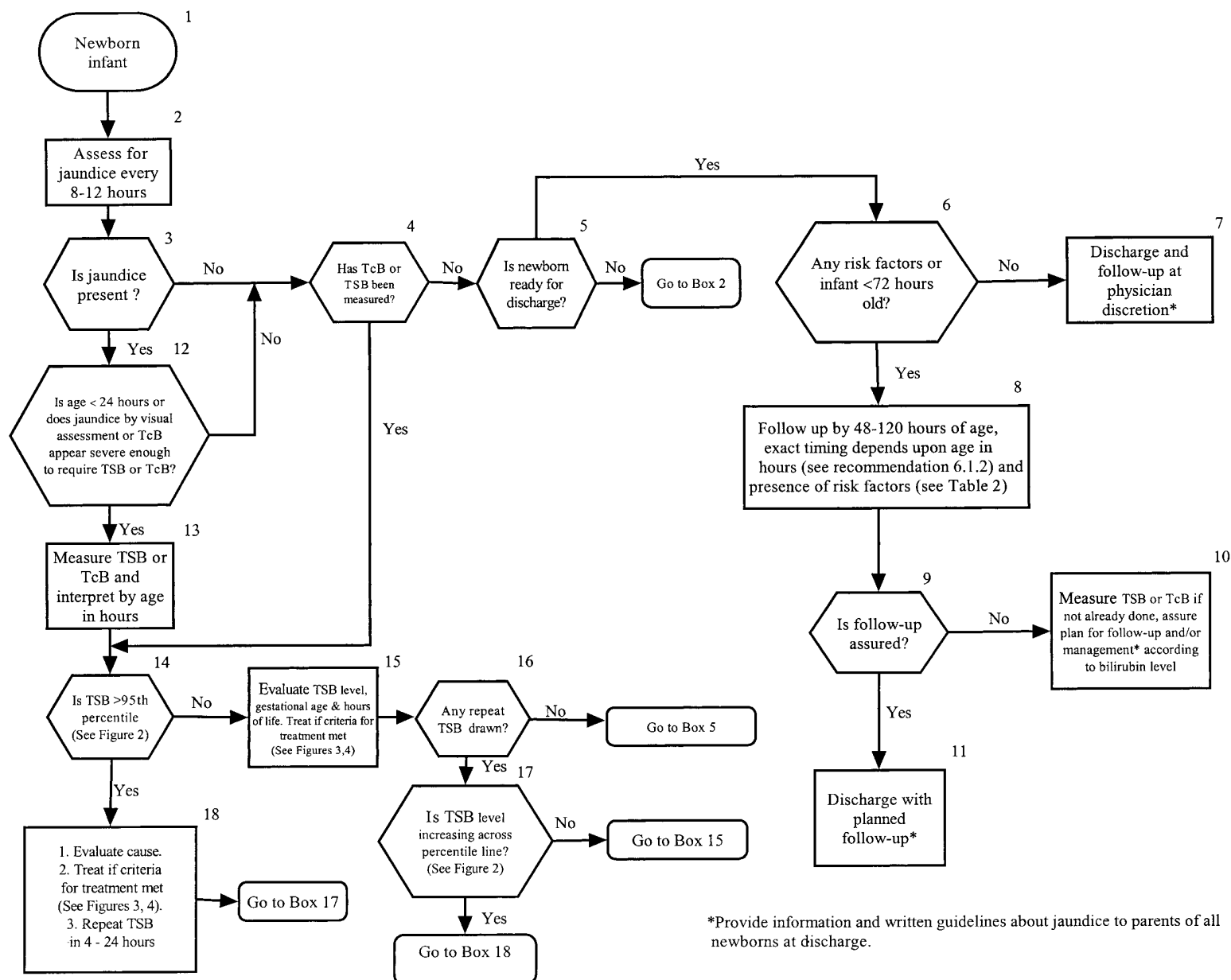


Fig 1. Algorithm for the management of jaundice in the newborn nursery.

formed in a well-lit room or, preferably, in daylight at a window. Jaundice is usually seen first in the face and progresses caudally to the trunk and extremities,²¹ but visual estimation of bilirubin levels from the degree of jaundice can lead to errors.^{22–24} In most infants with TSB levels of less than 15 mg/dL (257 μ mol/L), noninvasive TcB-measurement devices can provide a valid estimate of the TSB level.^{2,25–29} See Appendix 1 for additional information on the clinical evaluation of jaundice and the use of TcB measurements.

RECOMMENDATION 2.2.1: *Protocols for the assessment of jaundice should include the circumstances in which nursing staff can obtain a TcB level or order a TSB measurement (evidence quality D: benefits versus harms exceptional).*

Laboratory Evaluation

RECOMMENDATION 3.0: *A TcB and/or TSB measurement should be performed on every infant who is jaundiced in the first 24 hours after birth (Fig 1 and Table 1)³⁰ (evidence quality C: benefits exceed harms). The need for and timing of a repeat TcB or TSB measurement will depend on the zone in which the TSB falls (Fig 2),^{25,31} the age of the infant, and the evolution of the hyperbilirubinemia. Recommendations for TSB measurements after the age of 24 hours are provided in Fig 1 and Table 1.*

See Appendix 1 for capillary versus venous bilirubin levels.

RECOMMENDATION 3.1: *A TcB and/or TSB measurement should be performed if the jaundice appears excessive for the infant's age (evidence quality D: benefits versus harms exceptional). If there is any doubt about the degree of jaundice, the TSB or TcB should be measured. Visual estimation of bilirubin levels from the degree of jaundice can lead to errors, particularly in darkly pigmented infants (evidence quality C: benefits exceed harms).*

RECOMMENDATION 3.2: *All bilirubin levels should be interpreted according to the infant's age in hours (Fig 2) (evidence quality C: benefits exceed harms).*

Cause of Jaundice

RECOMMENDATION 4.1: *The possible cause of jaundice should be sought in an infant receiving phototherapy or whose TSB level is rising rapidly (ie, crossing percentiles [Fig 2]) and is not explained by the history and physical examination (evidence quality D: benefits versus harms exceptional).*

RECOMMENDATION 4.1.1: *Infants who have an elevation of direct-reacting or conjugated bilirubin should have a urinalysis and urine culture.³² Additional laboratory evaluation for sepsis should be performed if indicated by history and physical examination (evidence quality C: benefits exceed harms).*

See Appendix 1 for definitions of abnormal levels of direct-reacting and conjugated bilirubin.

RECOMMENDATION 4.1.2: *Sick infants and those who are jaundiced at or beyond 3 weeks should have a measurement of total and direct or conjugated bilirubin to identify cholestasis (Table 1) (evidence quality D: benefit versus harms exceptional). The results of the newborn thyroid and galactosemia screen should also be checked in these infants (evidence quality D: benefits versus harms exceptional).*

RECOMMENDATION 4.1.3: *If the direct-reacting or conjugated bilirubin level is elevated, additional evaluation for the causes of cholestasis is recommended (evidence quality C: benefits exceed harms).*

RECOMMENDATION 4.1.4: *Measurement of the glucose-6-phosphate dehydrogenase (G6PD) level is recommended for a jaundiced infant who is receiving phototherapy and whose family history or ethnic or geographic origin suggest the likelihood of G6PD deficiency or for an infant in whom the response to phototherapy is poor (Fig 3) (evidence quality C: benefits exceed harms).*

G6PD deficiency is widespread and frequently unrecognized, and although it is more common in the populations around the Mediterranean and in the Middle East, Arabian peninsula, Southeast Asia, and Africa, immigration and intermarriage have transformed G6PD deficiency into a global problem.^{33,34}

TABLE 1. Laboratory Evaluation of the Jaundiced Infant of 35 or More Weeks' Gestation

Indications	Assessments
Jaundice in first 24 h	Measure TcB and/or TSB
Jaundice appears excessive for infant's age	Measure TcB and/or TSB
Infant receiving phototherapy or TSB rising rapidly (ie, crossing percentiles [Fig 2]) and unexplained by history and physical examination	Blood type and Coombs' test, if not obtained with cord blood Complete blood count and smear Measure direct or conjugated bilirubin It is an option to perform reticulocyte count, G6PD, and ETCO ₂ if available Repeat TSB in 4–24 h depending on infant's age and TSB level
TSB concentration approaching exchange levels or not responding to phototherapy	Perform reticulocyte count, G6PD, albumin, ETCO ₂ if available
Elevated direct (or conjugated) bilirubin level	Do urinalysis and urine culture. Evaluate for sepsis if indicated by history and physical examination
Jaundice present at or beyond age 3 wk, or sick infant	Total and direct (or conjugated) bilirubin level If direct bilirubin elevated, evaluate for causes of cholestasis Check results of newborn thyroid and galactosemia screen, and evaluate infant for signs or symptoms of hypothyroidism

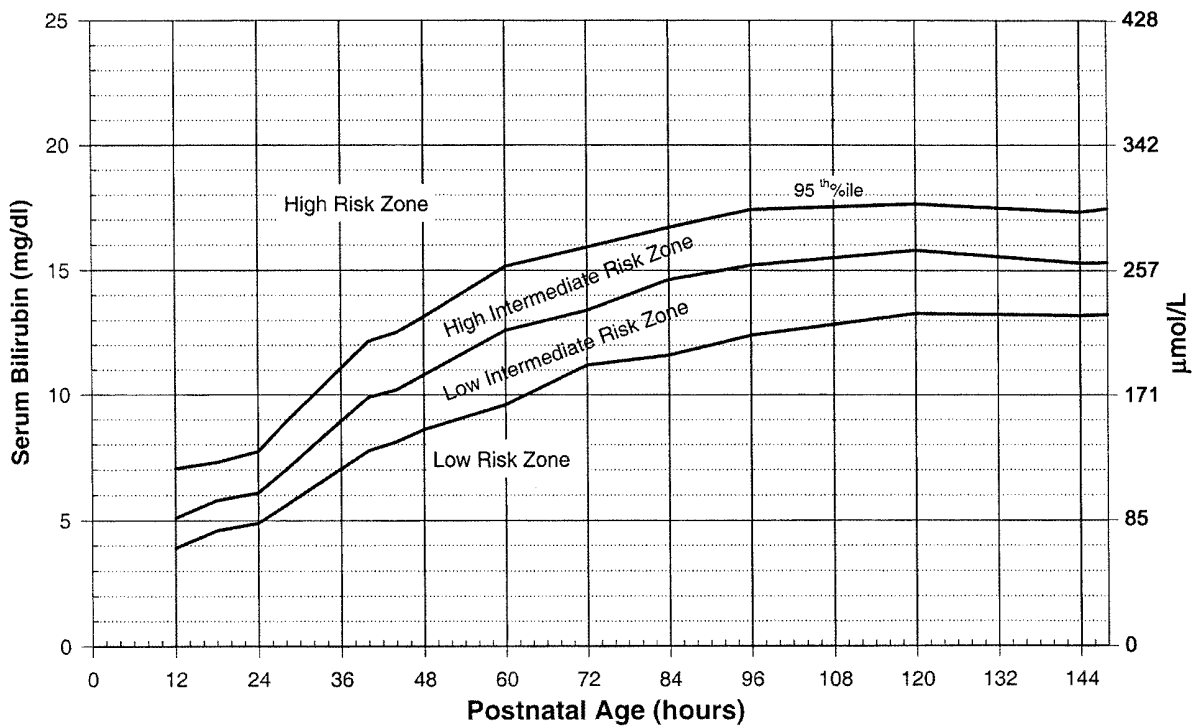


Fig 2. Nomogram for designation of risk in 2840 well newborns at 36 or more weeks' gestational age with birth weight of 2000 g or more or 35 or more weeks' gestational age and birth weight of 2500 g or more based on the hour-specific serum bilirubin values. The serum bilirubin level was obtained before discharge, and the zone in which the value fell predicted the likelihood of a subsequent bilirubin level exceeding the 95th percentile (high-risk zone) as shown in Appendix 1, Table 4. Used with permission from Bhutani et al.³¹ See Appendix 1 for additional information about this nomogram, which should not be used to represent the natural history of neonatal hyperbilirubinemia.

Furthermore, G6PD deficiency occurs in 11% to 13% of African Americans, and kernicterus has occurred in some of these infants.^{5,33} In a recent report, G6PD deficiency was considered to be the cause of hyperbilirubinemia in 19 of 61 (31.5%) infants who developed kernicterus.⁵ (See Appendix 1 for additional information on G6PD deficiency.)

Risk Assessment Before Discharge

RECOMMENDATION 5.1: Before discharge, every newborn should be assessed for the risk of developing severe hyperbilirubinemia, and all nurseries should establish protocols for assessing this risk. Such assessment is particularly important in infants who are discharged before the age of 72 hours (evidence quality C: benefits exceed harms).

RECOMMENDATION 5.1.1: The AAP recommends 2 clinical options used individually or in combination for the systematic assessment of risk: predischage measurement of the bilirubin level using TSB or TcB and/or assessment of clinical risk factors. Whether either or both options are used, appropriate follow-up after discharge is essential (evidence quality C: benefits exceed harms).

The best documented method for assessing the risk of subsequent hyperbilirubinemia is to measure the TSB or TcB level^{25,31,35–38} and plot the results on a nomogram (Fig 2). A TSB level can be obtained at the time of the routine metabolic screen, thus obviating the need for an additional blood sample. Some authors have suggested that a TSB measurement should be part of the routine screening of all newborns.^{5,31} An infant whose predischage TSB is in the

low-risk zone (Fig 2) is at very low risk of developing severe hyperbilirubinemia.^{5,38}

Table 2 lists those factors that are clinically signif-

TABLE 2. Risk Factors for Development of Severe Hyperbilirubinemia in Infants of 35 or More Weeks' Gestation (in Approximate Order of Importance)

Major risk factors	
Predischage TSB or TcB level in the high-risk zone (Fig 2) ^{25,31}	
Jaundice observed in the first 24 h ³⁰	
Blood group incompatibility with positive direct antiglobulin test, other known hemolytic disease (eg, G6PD deficiency), elevated ETCO _c	
Gestational age 35–36 wk ^{39,40}	
Previous sibling received phototherapy ^{40,41}	
Cephalohematoma or significant bruising ³⁹	
Exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive ^{39,40}	
East Asian race ^{39*}	
Minor risk factors	
Predischage TSB or TcB level in the high intermediate-risk zone ^{25,31}	
Gestational age 37–38 wk ^{39,40}	
Jaundice observed before discharge ⁴⁰	
Previous sibling with jaundice ^{40,41}	
Macrosomic infant of a diabetic mother ^{42,43}	
Maternal age ≥25 y ³⁹	
Male gender ^{39,40}	
Decreased risk (these factors are associated with decreased risk of significant jaundice, listed in order of decreasing importance)	
TSB or TcB level in the low-risk zone (Fig 2) ^{25,31}	
Gestational age ≥41 wk ³⁹	
Exclusive bottle feeding ^{39,40}	
Black race ^{38*}	
Discharge from hospital after 72 h ^{40,44}	

* Race as defined by mother's description.

icant and most frequently associated with an increase in the risk of severe hyperbilirubinemia. But, because these risk factors are common and the risk of hyperbilirubinemia is small, individually the factors are of limited use as predictors of significant hyperbilirubinemia.³⁹ Nevertheless, if no risk factors are present, the risk of severe hyperbilirubinemia is extremely low, and the more risk factors present, the greater the risk of severe hyperbilirubinemia.³⁹ The important risk factors most frequently associated with severe hyperbilirubinemia are breastfeeding, gestation below 38 weeks, significant jaundice in a previous sibling, and jaundice noted before discharge.^{39,40} A formula-fed infant of 40 or more weeks' gestation is at very low risk of developing severe hyperbilirubinemia.³⁹

Hospital Policies and Procedures

RECOMMENDATION 6.1: All hospitals should provide written and verbal information for parents at the time of discharge, which should include an explanation of jaundice, the need to monitor infants for jaundice, and advice on how monitoring should be done (evidence quality D: benefits versus harms exceptional).

An example of a parent-information handout is available in English and Spanish at www.aap.org/family/jaundicefaq.htm.

Follow-up

RECOMMENDATION 6.1.1: All infants should be examined by a qualified health care professional in the first few days after discharge to assess infant well-being and the presence or absence of jaundice. The timing and location of this assessment will be determined by the length of stay in the nursery, presence or absence of risk factors for hyperbilirubinemia (Table 2 and Fig 2), and risk of other neonatal problems (evidence quality C: benefits exceed harms).

Timing of Follow-up

RECOMMENDATION 6.1.2: Follow-up should be provided as follows:

Infant Discharged	Should Be Seen by Age
Before age 24 h	72 h
Between 24 and 47.9 h	96 h
Between 48 and 72 h	120 h

For some newborns discharged before 48 hours, 2 follow-up visits may be required, the first visit between 24 and 72 hours and the second between 72 and 120 hours. Clinical judgment should be used in determining follow-up. Earlier or more frequent follow-up should be provided for those who have risk factors for hyperbilirubinemia (Table 2), whereas those discharged with few or no risk factors can be seen after longer intervals (evidence quality C: benefits exceed harms).

RECOMMENDATION 6.1.3: If appropriate follow-up cannot be ensured in the presence of elevated risk for developing severe hyperbilirubinemia, it may be necessary to delay discharge either until appropriate follow-up can be ensured or the period of greatest risk has passed (72-96 hours) (evidence quality D: benefits versus harms exceptional).

Follow-up Assessment

RECOMMENDATION 6.1.4: The follow-up assessment should include the infant's weight and percent change from birth weight, adequacy of intake, the pattern of voiding and stooling, and the presence or absence of jaundice (evidence quality C: benefits exceed harms). Clinical judgment should be used to determine the need for a bilirubin measurement. If there is any doubt about the degree of jaundice, the TSB or TcB level should be measured. Visual estimation of bilirubin levels can lead to errors, particularly in darkly pigmented infants (evidence quality C: benefits exceed harms).

See Appendix 1 for assessment of the adequacy of intake in breastfeeding infants.

TREATMENT

Phototherapy and Exchange Transfusion

RECOMMENDATION 7.1: Recommendations for treatment are given in Table 3 and Figs 3 and 4 (evidence quality C: benefits exceed harms). If the TSB does not fall or continues to rise despite intensive phototherapy, it is very likely that hemolysis is occurring. The committee's recommendations for discontinuing phototherapy can be found in Appendix 2.

RECOMMENDATION 7.1.1: In using the guidelines for phototherapy and exchange transfusion (Figs 3 and 4), the direct-reacting (or conjugated) bilirubin level should not be subtracted from the total (evidence quality D: benefits versus harms exceptional).

In unusual situations in which the direct bilirubin level is 50% or more of the total bilirubin, there are no good data to provide guidance for therapy, and consultation with an expert in the field is recommended.

RECOMMENDATION 7.1.2: If the TSB is at a level at which exchange transfusion is recommended (Fig 4) or if the TSB level is 25 mg/dL (428 μ mol/L) or higher at any time, it is a medical emergency and the infant should be admitted immediately and directly to a hospital pediatric service for intensive phototherapy. These infants should not be referred to the emergency department, because it delays the initiation of treatment⁵⁴ (evidence quality C: benefits exceed harms).

RECOMMENDATION 7.1.3: Exchange transfusions should be performed only by trained personnel in a neonatal intensive care unit with full monitoring and resuscitation capabilities (evidence quality D: benefits versus harms exceptional).

RECOMMENDATION 7.1.4: In isoimmune hemolytic disease, administration of intravenous γ -globulin (0.5-1 g/kg over 2 hours) is recommended if the TSB is rising despite intensive phototherapy or the TSB level is within 2 to 3 mg/dL (34-51 μ mol/L) of the exchange level (Fig 4).⁵⁵ If necessary, this dose can be repeated in 12 hours (evidence quality B: benefits exceed harms).

Intravenous γ -globulin has been shown to reduce the need for exchange transfusions in Rh and ABO hemolytic disease.⁵⁵⁻⁵⁸ Although data are limited, it is reasonable to assume that intravenous γ -globulin will also be helpful in the other types of Rh hemolytic disease such as anti-C and anti-E.

TABLE 3. Example of a Clinical Pathway for Management of the Newborn Infant Readmitted for Phototherapy or Exchange Transfusion

Treatment
Use intensive phototherapy and/or exchange transfusion as indicated in Figs 3 and 4 (see Appendix 2 for details of phototherapy use)
Laboratory tests
TSB and direct bilirubin levels
Blood type (ABO, Rh)
Direct antibody test (Coombs')
Serum albumin
Complete blood cell count with differential and smear for red cell morphology
Reticulocyte count
ETCO _c (if available)
G6PD if suggested by ethnic or geographic origin or if poor response to phototherapy
Urine for reducing substances
If history and/or presentation suggest sepsis, perform blood culture, urine culture, and cerebrospinal fluid for protein, glucose, cell count, and culture
Interventions
If TSB ≥ 25 mg/dL (428 $\mu\text{mol/L}$) or ≥ 20 mg/dL (342 $\mu\text{mol/L}$) in a sick infant or infant < 38 wk gestation, obtain a type and crossmatch, and request blood in case an exchange transfusion is necessary
In infants with isoimmune hemolytic disease and TSB level rising in spite of intensive phototherapy or within 2–3 mg/dL (34–51 $\mu\text{mol/L}$) of exchange level (Fig 4), administer intravenous immunoglobulin 0.5–1 g/kg over 2 h and repeat in 12 h if necessary
If infant's weight loss from birth is $> 12\%$ or there is clinical or biochemical evidence of dehydration, recommend formula or expressed breast milk. If oral intake is in question, give intravenous fluids.
For infants receiving intensive phototherapy
Breastfeed or bottle-feed (formula or expressed breast milk) every 2–3 h
If TSB ≥ 25 mg/dL (428 $\mu\text{mol/L}$), repeat TSB within 2–3 h
If TSB 20–25 mg/dL (342–428 $\mu\text{mol/L}$), repeat within 3–4 h. If TSB < 20 mg/dL (342 $\mu\text{mol/L}$), repeat in 4–6 h. If TSB continues to fall, repeat in 8–12 h
If TSB is not decreasing or is moving closer to level for exchange transfusion or the TSB/albumin ratio exceeds levels shown in Fig 4, consider exchange transfusion (see Fig 4 for exchange transfusion recommendations)
When TSB is < 13 –14 mg/dL (239 $\mu\text{mol/L}$), discontinue phototherapy
Depending on the cause of the hyperbilirubinemia, it is an option to measure TSB 24 h after discharge to check for rebound

Serum Albumin Levels and the Bilirubin/Albumin Ratio

RECOMMENDATION 7.1.5: *It is an option to measure the serum albumin level and consider an albumin level of less than 3.0 g/dL as one risk factor for lowering the threshold for phototherapy use (see Fig 3) (evidence quality D: benefits versus risks exceptional).*

RECOMMENDATION 7.1.6: *If an exchange transfusion is being considered, the serum albumin level should be measured and the bilirubin/albumin (B/A) ratio used in conjunction with the TSB level and other factors in determining the need for exchange transfusion (see Fig 4) (evidence quality D: benefits versus harms exceptional).*

The recommendations shown above for treating hyperbilirubinemia are based primarily on TSB levels and other factors that affect the risk of bilirubin encephalopathy. This risk might be increased by a prolonged (rather than a brief) exposure to a certain TSB level.^{59,60} Because the published data that address this issue are limited, however, it is not possible to provide specific recommendations for intervention based on the duration of hyperbilirubinemia.

See Appendix 1 for the basis for recommendations 7.1 through 7.1.6 and for the recommendations provided in Figs 3 and 4. Appendix 1 also contains a discussion of the risks of exchange transfusion and the use of B/A binding.

Acute Bilirubin Encephalopathy

RECOMMENDATION 7.1.7: *Immediate exchange transfusion is recommended in any infant who is jaun-*

diced and manifests the signs of the intermediate to advanced stages of acute bilirubin encephalopathy^{61,62} (hypertonia, arching, retrocollis, opisthotonos, fever, high-pitched cry) even if the TSB is falling (evidence quality D: benefits versus risks exceptional).

Phototherapy

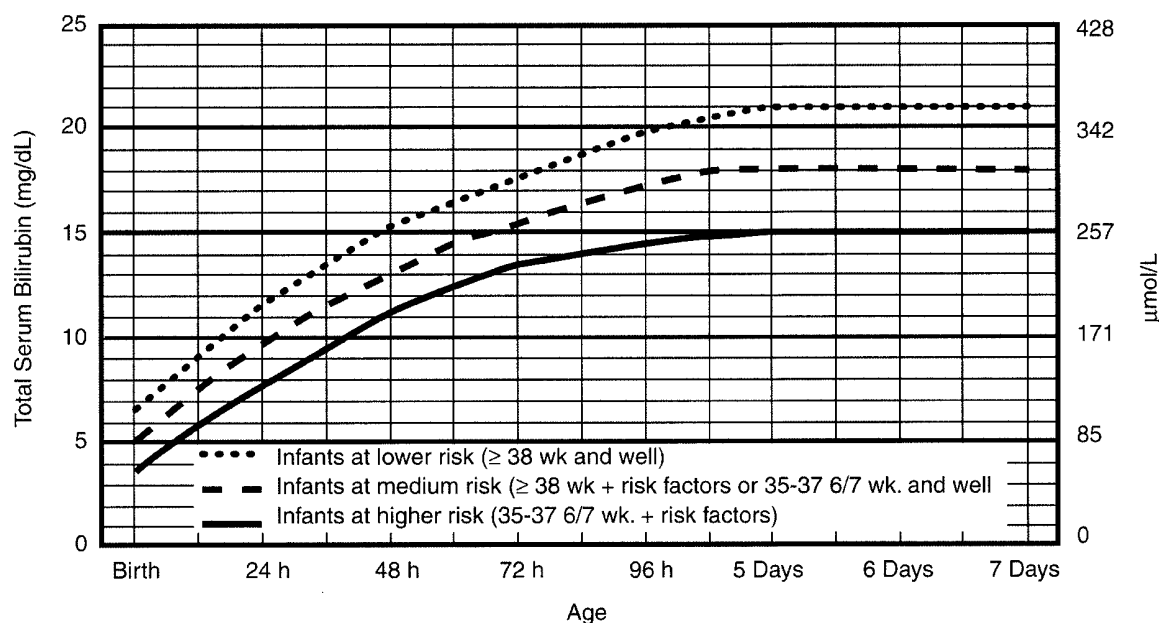
RECOMMENDATION 7.2: *All nurseries and services treating infants should have the necessary equipment to provide intensive phototherapy (see Appendix 2) (evidence quality D: benefits exceed risks).*

Outpatient Management of the Jaundiced Breastfed Infant

RECOMMENDATION 7.3: *In breastfed infants who require phototherapy (Fig 3), the AAP recommends that, if possible, breastfeeding should be continued (evidence quality C: benefits exceed harms). It is also an option to interrupt temporarily breastfeeding and substitute formula. This can reduce bilirubin levels and/or enhance the efficacy of phototherapy^{63–65} (evidence quality B: benefits exceed harms). In breastfed infants receiving phototherapy, supplementation with expressed breast milk or formula is appropriate if the infant's intake seems inadequate, weight loss is excessive, or the infant seems dehydrated.*

IMPLEMENTATION STRATEGIES

The Institute of Medicine¹¹ recommends a dramatic change in the way the US health care system



- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin.
- Risk factors = isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis, or albumin < 3.0 g/dL (if measured)
- For well infants 35-37 6/7 wk can adjust TSB levels for intervention around the medium risk line. It is an option to intervene at lower TSB levels for infants closer to 35 wks and at higher TSB levels for those closer to 37 6/7 wk.
- It is an option to provide conventional phototherapy in hospital or at home at TSB levels 2-3 mg/dL (35-50 μmol/L) below those shown but home phototherapy should not be used in any infant with risk factors.

Fig 3. Guidelines for phototherapy in hospitalized infants of 35 or more weeks' gestation.

Note: These guidelines are based on limited evidence and the levels shown are approximations. The guidelines refer to the use of intensive phototherapy which should be used when the TSB exceeds the line indicated for each category. Infants are designated as "higher risk" because of the potential negative effects of the conditions listed on albumin binding of bilirubin,⁴⁵⁻⁴⁷ the blood-brain barrier,⁴⁸ and the susceptibility of the brain cells to damage by bilirubin.⁴⁸

"Intensive phototherapy" implies irradiance in the blue-green spectrum (wavelengths of approximately 430–490 nm) of at least 30 μ W/cm² per nm (measured at the infant's skin directly below the center of the phototherapy unit) and delivered to as much of the infant's surface area as possible. Note that irradiance measured below the center of the light source is much greater than that measured at the periphery. Measurements should be made with a radiometer specified by the manufacturer of the phototherapy system.

See Appendix 2 for additional information on measuring the dose of phototherapy, a description of intensive phototherapy, and of light sources used. If total serum bilirubin levels approach or exceed the exchange transfusion line (Fig 4), the sides of the bassinet, incubator, or warmer should be lined with aluminum foil or white material.⁵⁰ This will increase the surface area of the infant exposed and increase the efficacy of phototherapy.⁵¹

If the total serum bilirubin does not decrease or continues to rise in an infant who is receiving intensive phototherapy, this strongly suggests the presence of hemolysis.

Infants who receive phototherapy and have an elevated direct-reacting or conjugated bilirubin level (cholestatic jaundice) may develop the bronze-baby syndrome. See Appendix 2 for the use of phototherapy in these infants.

ensures the safety of patients. The perspective of safety as a purely individual responsibility must be replaced by the concept of safety as a property of systems. Safe systems are characterized by a shared knowledge of the goal, a culture emphasizing safety, the ability of each person within the system to act in a manner that promotes safety, minimizing the use of memory, and emphasizing the use of standard procedures (such as checklists), and the involvement of patients/families as partners in the process of care.

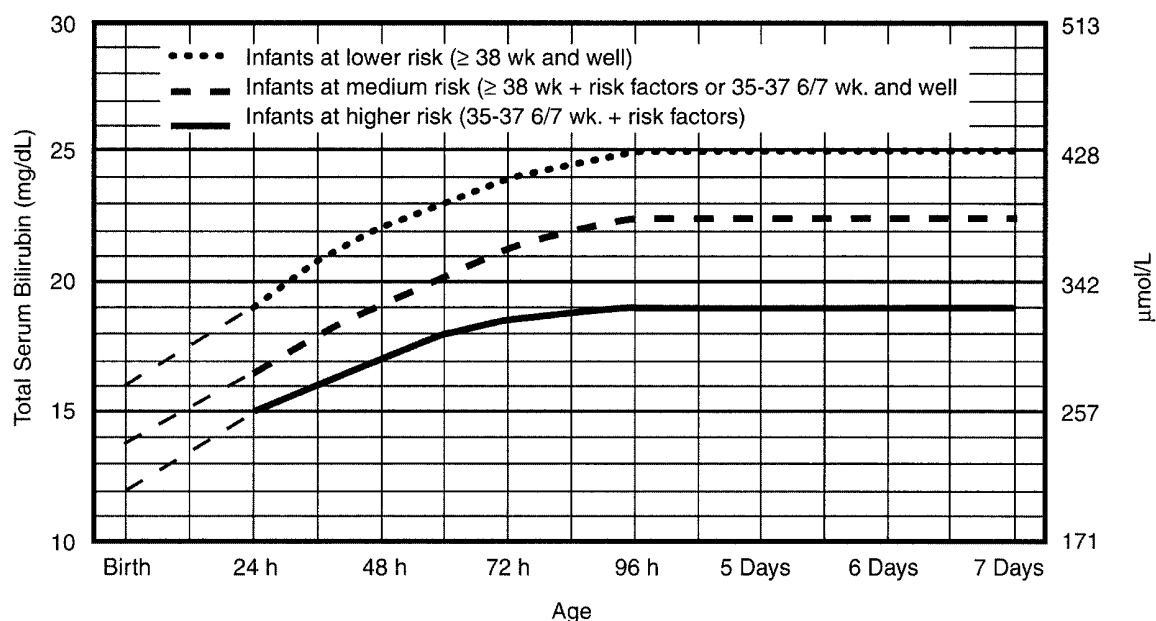
These principles can be applied to the challenge of preventing severe hyperbilirubinemia and kernicterus. A systematic approach to the implementation of these guidelines should result in greater safety. Such approaches might include

- The establishment of standing protocols for nursing assessment of jaundice, including testing TcB and TSB levels, without requiring physician orders.
- Checklists or reminders associated with risk factors, age at discharge, and laboratory test results that provide guidance for appropriate follow-up.
- Explicit educational materials for parents (a key component of all AAP guidelines) concerning the identification of newborns with jaundice.

FUTURE RESEARCH

Epidemiology of Bilirubin-Induced Central Nervous System Damage

There is a need for appropriate epidemiologic data to document the incidence of kernicterus in the newborn population, the incidence of other adverse effects attributable to hyperbilirubinemia and its management, and the number of infants whose TSB levels exceed 25 or 30 mg/dL (428-513 μ mol/L). Organizations such as the Centers for Disease Control and Prevention should implement strategies for appropriate data gathering to identify the number of



- The dashed lines for the first 24 hours indicate uncertainty due to a wide range of clinical circumstances and a range of responses to phototherapy.
- Immediate exchange transfusion is recommended if infant shows signs of acute bilirubin encephalopathy (hypertonia, arching, retrocollis, opisthotonos, fever, high pitched cry) or if TSB is ≥ 5 mg/dL (85 $\mu\text{mol/L}$) above these lines.
- Risk factors - isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis.
- Measure serum albumin and calculate B/A ratio (See legend)
- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin
- If infant is well and 35-37 6/7 wk (median risk) can individualize TSB levels for exchange based on actual gestational age.

Fig 4. Guidelines for exchange transfusion in infants 35 or more weeks' gestation.

Note that these suggested levels represent a consensus of most of the committee but are based on limited evidence, and the levels shown are approximations. See ref. 3 for risks and complications of exchange transfusion. During birth hospitalization, exchange transfusion is recommended if the TSB rises to these levels despite intensive phototherapy. For readmitted infants, if the TSB level is above the exchange level, repeat TSB measurement every 2 to 3 hours and consider exchange if the TSB remains above the levels indicated after intensive phototherapy for 6 hours.

The following B/A ratios can be used together with but in not in lieu of the TSB level as an additional factor in determining the need for exchange transfusion⁵²:

Risk Category	B/A Ratio at Which Exchange Transfusion Should be Considered	
	TSB mg/dL/Alb, g/dL	TSB $\mu\text{mol/L}$ /Alb, $\mu\text{mol/L}$
Infants ≥ 38 0/7 wk	8.0	0.94
Infants 35 0/7–36 6/7 wk and well or ≥ 38 0/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	7.2	0.84
Infants 35 0/7–37 6/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	6.8	0.80

If the TSB is at or approaching the exchange level, send blood for immediate type and crossmatch. Blood for exchange transfusion is modified whole blood (red cells and plasma) crossmatched against the mother and compatible with the infant.⁵³

infants who develop serum bilirubin levels above 25 or 30 mg/dL (428–513 $\mu\text{mol/L}$) and those who develop acute and chronic bilirubin encephalopathy. This information will help to identify the magnitude of the problem; the number of infants who need to be screened and treated to prevent 1 case of kernicterus; and the risks, costs, and benefits of different strategies for prevention and treatment of hyperbilirubinemia. In the absence of these data, recommendations for intervention cannot be considered definitive.

Effect of Bilirubin on the Central Nervous System

The serum bilirubin level by itself, except when it is extremely high and associated with bilirubin encephalopathy, is an imprecise indicator of long-term neurodevelopmental outcome.² Additional studies are needed on the relationship between central nervous system damage and the duration of hyperbilirubinemia, the binding of bilirubin to albumin, and changes seen in the brainstem auditory evoked response. These studies could help to better identify

risk, clarify the effect of bilirubin on the central nervous system, and guide intervention.

Identification of Hemolysis

Because of their poor specificity and sensitivity, the standard laboratory tests for hemolysis (Table 1) are frequently unhelpful.^{66,67} However, end-tidal carbon monoxide, corrected for ambient carbon monoxide (ETCO_c), levels can confirm the presence or absence of hemolysis, and measurement of ETCO_c is the only clinical test that provides a direct measurement of the rate of heme catabolism and the rate of bilirubin production.^{68,69} Thus, ETCO_c may be helpful in determining the degree of surveillance needed and the timing of intervention. It is not yet known, however, how ETCO_c measurements will affect management.

Nomograms and the Measurement of Serum and TcB

It would be useful to develop an age-specific (by hour) nomogram for TSB in populations of newborns that differ with regard to risk factors for hyperbilirubinemia. There is also an urgent need to improve the precision and accuracy of the measurement of TSB in the clinical laboratory.^{70,71} Additional studies are also needed to develop and validate noninvasive (transcutaneous) measurements of serum bilirubin and to understand the factors that affect these measurements. These studies should also assess the cost-effectiveness and reproducibility of TcB measurements in clinical practice.²

Pharmacologic Therapy

There is now evidence that hyperbilirubinemia can be effectively prevented or treated with tin-mesoporphyrin,⁷²⁻⁷⁵ a drug that inhibits the production of heme oxygenase. Tin-mesoporphyrin is not approved by the US Food and Drug Administration. If approved, tin-mesoporphyrin could find immediate application in preventing the need for exchange transfusion in infants who are not responding to phototherapy.⁷⁵

Dissemination and Monitoring

Research should be directed toward methods for disseminating the information contained in this guideline to increase awareness on the part of physicians, residents, nurses, and parents concerning the issues of neonatal hyperbilirubinemia and strategies for its management. In addition, monitoring systems should be established to identify the impact of these guidelines on the incidence of acute bilirubin encephalopathy and kernicterus and the use of phototherapy and exchange transfusions.

CONCLUSIONS

Kernicterus is still occurring but should be largely preventable if health care personnel follow the recommendations listed in this guideline. These recommendations emphasize the importance of universal, systematic assessment for the risk of severe hyperbi-

lirubinemia, close follow-up, and prompt intervention, when necessary.

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APPENDIX 1: Additional Notes

Definitions of Quality of Evidence and Balance of Benefits and Harms

The Steering Committee on Quality Improvement and Management categorizes evidence quality in 4 levels:

1. Well-designed, randomized, controlled trials or diagnostic studies on relevant populations
2. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelming, consistent evidence from observational studies
3. Observational studies (case-control and cohort design)
4. Expert opinion, case reports, reasoning from first principles

The AAP defines evidence-based recommendations as follows:¹

- Strong recommendation: the committee believes that the benefits of the recommended approach clearly exceed the harms of that approach and that the quality of the supporting evidence is either excellent or impossible to obtain. Clinicians should follow these recommendations unless a clear and compelling rationale for an alternative approach is present.
- Recommendation: the committee believes that the benefits exceed the harms, but the quality of evidence on which this recommendation is based is not as strong. Clinicians should also generally follow these recommendations but should be alert to new information and sensitive to patient prefer-

ences. In this guideline, the term “should” implies a recommendation by the committee.

- Option: either the quality of the evidence that exists is suspect or well-performed studies have shown little clear advantage to one approach over another. Patient preference should have a substantial role in influencing clinical decision-making when a policy is described as an option.
- No recommendation: there is a lack of pertinent evidence and the anticipated balance of benefits and harms is unclear.

Anticipated Balance Between Benefits and Harms

The presence of clear benefits or harms supports stronger statements for or against a course of action. In some cases, however, recommendations are made when analysis of the balance of benefits and harms provides an exceptional dysequilibrium and it would be unethical or impossible to perform clinical trials to “prove” the point. In these cases the balance of benefit and harm is termed “exceptional.”

Clinical Manifestations of Acute Bilirubin Encephalopathy and Kernicterus

Acute Bilirubin Encephalopathy

In the early phase of acute bilirubin encephalopathy, severely jaundiced infants become lethargic and hypotonic and suck poorly.^{2,3} The intermediate phase is characterized by moderate stupor, irritability, and hypertonia. The infant may develop a fever and high-pitched cry, which may alternate with drowsiness and hypotonia. The hypertonia is manifested by backward arching of the neck (retrocollis) and trunk (opisthotonos). There is anecdotal evidence that an emergent exchange transfusion at this stage, in some cases, might reverse the central nervous system changes.⁴ The advanced phase, in which central nervous system damage is probably irreversible, is characterized by pronounced retrocollis-opisthotonos, shrill cry, no feeding, apnea, fever, deep stupor to coma, sometimes seizures, and death.^{2,3,5}

Kernicterus

In the chronic form of bilirubin encephalopathy, surviving infants may develop a severe form of athetoid cerebral palsy, auditory dysfunction, dental-enamel dysplasia, paralysis of upward gaze, and, less often, intellectual and other handicaps. Most infants who develop kernicterus have manifested some or all of the signs listed above in the acute phase of bilirubin encephalopathy. However, occasionally there are infants who have developed very high bilirubin levels and, subsequently, the signs of kernicterus but have exhibited few, if any, antecedent clinical signs of acute bilirubin encephalopathy.^{3,5,6}

Clinical Evaluation of Jaundice and TcB Measurements

Jaundice is usually seen in the face first and progresses caudally to the trunk and extremities,⁷ but because visual estimation of bilirubin levels from the degree of jaundice can lead to errors,^{8–10} a low threshold should be used for measuring the TSB.

Devices that provide a noninvasive TcB measurement have proven very useful as screening tools,¹¹ and newer instruments give measurements that provide a valid estimate of the TSB level.^{12–17} Studies using the new TcB-measurement instruments are limited, but the data published thus far suggest that in most newborn populations, these instruments generally provide measurements within 2 to 3 mg/dL (34–51 $\mu\text{mol/L}$) of the TSB and can replace a measurement of serum bilirubin in many circumstances, particularly for TSB levels less than 15 mg/dL (257 $\mu\text{mol/L}$).^{12–17} Because phototherapy “bleaches” the skin, both visual assessment of jaundice and TcB measurements in infants undergoing phototherapy are not reliable. In addition, the ability of transcutaneous instruments to provide accurate measurements in different racial groups requires additional study.^{18,19} The limitations of the accuracy and reproducibility of TSB measurements in the clinical laboratory^{20–22} must also be recognized and are discussed in the technical report.²³

Capillary Versus Venous Serum Bilirubin Measurement

Almost all published data regarding the relationship of TSB levels to kernicterus or developmental outcome are based on capillary blood TSB levels. Data regarding the differences between capillary and venous TSB levels are conflicting.^{24,25} In 1 study the capillary TSB levels were higher, but in another they were lower than venous TSB levels.^{24,25} Thus, obtaining a venous sample to “confirm” an elevated capillary TSB level is not recommended, because it will delay the initiation of treatment.

Direct-Reacting and Conjugated Bilirubin

Although commonly used interchangeably, direct-reacting bilirubin is not the same as conjugated bilirubin. Direct-reacting bilirubin is the bilirubin that reacts directly (without the addition of an accelerating agent) with diazotized sulfanilic acid. Conjugated bilirubin is bilirubin made water soluble by binding with glucuronic acid in the liver. Depending on the technique used, the clinical laboratory will report total and direct-reacting or unconjugated and conjugated bilirubin levels. In this guideline and for clinical purposes, the terms may be used interchangeably.

Abnormal Direct and Conjugated Bilirubin Levels

Laboratory measurement of direct bilirubin is not precise,²⁶ and values between laboratories can vary widely. If the TSB is at or below 5 mg/dL (85 $\mu\text{mol/L}$), a direct or conjugated bilirubin of more than 1.0

mg/dL (17.1 $\mu\text{mol/L}$) is generally considered abnormal. For TSB values higher than 5 mg/dL (85 $\mu\text{mol/L}$), a direct bilirubin of more than 20% of the TSB is considered abnormal. If the hospital laboratory measures conjugated bilirubin using the Vitros (formerly Ektachem) system (Ortho-Clinical Diagnostics, Raritan, NJ), any value higher than 1 mg/dL is considered abnormal.

Assessment of Adequacy of Intake in Breastfeeding Infants

The data from a number of studies^{27–34} indicate that unsupplemented, breastfed infants experience their maximum weight loss by day 3 and, on average, lose $6.1\% \pm 2.5\%$ (SD) of their birth weight. Thus, ~5% to 10% of fully breastfed infants lose 10% or more of their birth weight by day 3, suggesting that adequacy of intake should be evaluated and the infant monitored if weight loss is more than 10%.³⁵ Evidence of adequate intake in breastfed infants also includes 4 to 6 thoroughly wet diapers in 24 hours and the passage of 3 to 4 stools per day by the fourth day. By the third to fourth day, the stools in adequately breastfed infants should have changed from meconium to a mustard yellow, mushy stool.³⁶ The above assessment will also help to identify breastfed infants who are at risk for dehydration because of inadequate intake.

Nomogram for Designation of Risk

Note that this nomogram (Fig 2) does not describe the natural history of neonatal hyperbilirubinemia, particularly after 48 to 72 hours, for which, because of sampling bias, the lower zones are spuriously elevated.³⁷ This bias, however, will have much less effect on the high-risk zone (95th percentile in the study).³⁸

G6PD Dehydrogenase Deficiency

It is important to look for G6PD deficiency in infants with significant hyperbilirubinemia, because some may develop a sudden increase in the TSB. In addition, G6PD-deficient infants require intervention at lower TSB levels (Figs 3 and 4). It should be noted also that in the presence of hemolysis, G6PD levels can be elevated, which may obscure the diagnosis in the newborn period so that a normal level in a hemolyzing neonate does not rule out G6PD deficiency.³⁹ If G6PD deficiency is strongly suspected, a repeat level should be measured when the infant is 3 months old. It is also recognized that immediate laboratory determination of G6PD is generally not available in most US hospitals, and thus translating the above information into clinical practice is cur-

TABLE 4. Risk Zone as a Predictor of Hyperbilirubinemia³⁹

TSB Before Discharge	Newborns (Total = 2840), <i>n</i> (%)	Newborns Who Subsequently Developed a TSB Level >95th Percentile, <i>n</i> (%)
High-risk zone (>95th percentile)	172 (6.0)	68 (39.5)
High intermediate-risk zone	356 (12.5)	46 (12.9)
Low intermediate-risk zone	556 (19.6)	12 (2.26)
Low-risk zone	1756 (61.8)	0

rently difficult. Nevertheless, practitioners are reminded to consider the diagnosis of G6PD deficiency in infants with severe hyperbilirubinemia, particularly if they belong to the population groups in which this condition is prevalent. This is important in the African American population, because these infants, as a group, have much lower TSB levels than white or Asian infants.^{40,41} Thus, severe hyperbilirubinemia in an African American infant should always raise the possibility of G6PD deficiency.

Basis for the Recommendations 7.1.1 Through 7.1.6 and Provided in Figs 3 and 4

Ideally, recommendations for when to implement phototherapy and exchange transfusions should be based on estimates of when the benefits of these interventions exceed their risks and cost. The evidence for these estimates should come from randomized trials or systematic observational studies. Unfortunately, there is little such evidence on which to base these recommendations. As a result, treatment guidelines must necessarily rely on more uncertain estimates and extrapolations. For a detailed discussion of this question, please see "An Evidence-Based Review of Important Issues Concerning Neonatal Hyperbilirubinemia."²³

The recommendations for phototherapy and exchange transfusion are based on the following principles:

- The main demonstrated value of phototherapy is that it reduces the risk that TSB levels will reach a level at which exchange transfusion is recommended.^{42–44} Approximately 5 to 10 infants with TSB levels between 15 and 20 mg/dL (257–342 $\mu\text{mol/L}$) will receive phototherapy to prevent the TSB in 1 infant from reaching 20 mg/dL (the number needed to treat).¹² Thus, 8 to 9 of every 10 infants with these TSB levels will not reach 20 mg/dL (342 $\mu\text{mol/L}$) even if they are not treated. Phototherapy has proven to be a generally safe procedure, although rare complications can occur (see Appendix 2).
- Recommended TSB levels for exchange transfusion (Fig 4) are based largely on the goal of keeping TSB levels below those at which kernicterus has been reported.^{12,45–48} In almost all cases, exchange transfusion is recommended only after phototherapy has failed to keep the TSB level below the exchange transfusion level (Fig 4).
- The recommendations to use phototherapy and exchange transfusion at lower TSB levels for infants of lower gestation and those who are sick are based on limited observations suggesting that sick infants (particularly those with the risk factors listed in Figs 3 and 4)^{49–51} and those of lower gestation^{51–54} are at greater risk for developing kernicterus at lower bilirubin levels than are well infants of more than 38 6/7 weeks' gestation. Nevertheless, other studies have not confirmed all of these associations.^{52,55,56} There is no doubt, however, that infants at 35 to 37 6/7 weeks' gestation are at a much greater risk of developing very high

TSB levels.^{57,58} Intervention for these infants is based on this risk as well as extrapolations from more premature, lower birth-weight infants who do have a higher risk of bilirubin toxicity.^{52,53}

- For all newborns, treatment is recommended at lower TSB levels at younger ages because one of the primary goals of treatment is to prevent additional increases in the TSB level.

Subtle Neurologic Abnormalities Associated With Hyperbilirubinemia

There are several studies demonstrating measurable transient changes in brainstem-evoked potentials, behavioral patterns, and the infant's cry^{59–63} associated with TSB levels of 15 to 25 mg/dL (257–428 $\mu\text{mol/L}$). In these studies, the abnormalities identified were transient and disappeared when the serum bilirubin levels returned to normal with or without treatment.^{59,60,62,63}

A few cohort studies have found an association between hyperbilirubinemia and long-term adverse neurodevelopmental effects that are more subtle than kernicterus.^{64–67} Current studies, however, suggest that although phototherapy lowers the TSB levels, it has no effect on these long-term neurodevelopmental outcomes.^{68–70}

Risks of Exchange Transfusion

Because exchange transfusions are now rarely performed, the risks of morbidity and mortality associated with the procedure are difficult to quantify. In addition, the complication rates listed below may not be generalizable to the current era if, like most procedures, frequency of performance is an important determinant of risk. Death associated with exchange transfusion has been reported in approximately 3 in 1000 procedures,^{71,72} although in otherwise well infants of 35 or more weeks' gestation, the risk is probably much lower.^{71–73} Significant morbidity (apnea, bradycardia, cyanosis, vasospasm, thrombosis, necrotizing enterocolitis) occurs in as many as 5% of exchange transfusions,⁷¹ and the risks associated with the use of blood products must always be considered.⁷⁴ Hypoxic-ischemic encephalopathy and acquired immunodeficiency syndrome have occurred in otherwise healthy infants receiving exchange transfusions.^{73,75}

Serum Albumin Levels and the B/A Ratio

The legends to Figs 3 and 4 and recommendations 7.1.5 and 7.1.6 contain references to the serum albumin level and the B/A ratio as factors that can be considered in the decision to initiate phototherapy (Fig 3) or perform an exchange transfusion (Fig 4). Bilirubin is transported in the plasma tightly bound to albumin, and the portion that is unbound or loosely bound can more readily leave the intravascular space and cross the intact blood-brain barrier.⁷⁶ Elevations of unbound bilirubin (UB) have been associated with kernicterus in sick preterm newborns.^{77,78} In addition, elevated UB concentrations are more closely associated than TSB levels with transient abnormalities in the audiometric brainstem response in term⁷⁹ and preterm⁸⁰ infants. Long-term

studies relating B/A binding in infants to developmental outcome are limited and conflicting.^{69,81,82} In addition, clinical laboratory measurement of UB is not currently available in the United States.

The ratio of bilirubin (mg/dL) to albumin (g/dL) does correlate with measured UB in newborns⁸³ and can be used as an approximate surrogate for the measurement of UB. It must be recognized, however, that both albumin levels and the ability of albumin to bind bilirubin vary significantly between newborns.^{83,84} Albumin binding of bilirubin is impaired in sick infants,^{84–86} and some studies show an increase in binding with increasing gestational^{86,87} and postnatal^{87,88} age, but others have not found a significant effect of gestational age on binding.⁸⁹ Furthermore, the risk of bilirubin encephalopathy is unlikely to be a simple function of the TSB level or the concentration of UB but is more likely a combination of both (ie, the total amount of bilirubin available [the miscible pool of bilirubin] as well as the tendency of bilirubin to enter the tissues [the UB concentration]).⁸³ An additional factor is the possible susceptibility of the cells of the central nervous system to damage by bilirubin.⁹⁰ It is therefore a clinical option to use the B/A ratio together with, but not in lieu of, the TSB level as an additional factor in determining the need for exchange transfusion⁸³ (Fig 4).

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APPENDIX 2: Phototherapy

There is no standardized method for delivering phototherapy. Phototherapy units vary widely, as do the types of lamps used in the units. The efficacy of phototherapy depends on the dose of phototherapy administered as well as a number of clinical factors (Table 5).¹

Measuring the Dose of Phototherapy

Table 5 shows the radiometric quantities used in measuring the phototherapy dose. The quantity most commonly reported in the literature is the spectral irradiance. In the nursery, spectral irradiance can be measured by using commercially available radiometers. These instruments take a single measurement across a band of wavelengths, typically 425 to 475 or 400 to 480 nm. Unfortunately, there is no standardized method for reporting phototherapy dosages in the clinical literature, so it is difficult to compare published studies on the efficacy of phototherapy and manufacturers' data for the irradiance produced by different systems.² Measurements of irradiance from the same system, using different radiometers,

TABLE 5. Factors That Affect the Dose and Efficacy of Phototherapy

Factor	Mechanism/Clinical Relevance	Implementation and Rationale	Clinical Application
Spectrum of light emitted	Blue-green spectrum is most effective. At these wavelengths, light penetrates skin well and is absorbed maximally by bilirubin.	Special blue fluorescent tubes or other light sources that have most output in the blue-green spectrum and are most effective in lowering TSB.	Use special blue tubes or LED light source with output in blue-green spectrum for intensive PT.
Spectral irradiance (irradiance in certain wavelength band) delivered to surface of infant	↑ irradiance → ↑ rate of decline in TSB	Irradiance is measured with a radiometer as $\mu\text{W}/\text{cm}^2$ per nm. Standard PT units deliver 8–10 $\mu\text{W}/\text{cm}^2$ per nm (Fig 6). Intensive PT requires >30 $\mu\text{W}/\text{cm}^2$ per nm.	If special blue fluorescent tubes are used, bring tubes as close to infant as possible to increase irradiance (Fig 6). Note: This cannot be done with halogen lamps because of the danger of burn. Special blue tubes 10–15 cm above the infant will produce an irradiance of at least 35 $\mu\text{W}/\text{cm}^2$ per nm.
Spectral power (average spectral irradiance across surface area)	↑ surface area exposed → ↑ rate of decline in TSB	For intensive PT, expose maximum surface area of infant to PT.	Place lights above and fiber-optic pad or special blue fluorescent tubes* below the infant. For maximum exposure, line sides of bassinet, warmer bed, or incubator with aluminum foil.
Cause of jaundice	PT is likely to be less effective if jaundice is due to hemolysis or if cholestasis is present. (↑ direct bilirubin)		When hemolysis is present, start PT at lower TSB levels. Use intensive PT. Failure of PT suggests that hemolysis is the cause of jaundice. If ↑ direct bilirubin, watch for bronze baby syndrome or blistering.
TSB level at start of PT	The higher the TSB, the more rapid the decline in TSB with PT.		Use intensive PT for higher TSB levels. Anticipate a more rapid decrease in TSB when TSB >20 mg/dL (342 $\mu\text{mol}/\text{L}$).

PT indicates phototherapy; LED, light-emitting diode.

* Available in the Olympic BiliBassinet (Olympic Medical, Seattle, WA).

can also produce significantly different results. The width of the phototherapy lamp's emissions spectrum (narrow versus broad) will affect the measured irradiance. Measurements under lights with a very focused emission spectrum (eg, blue light-emitting diode) will vary significantly from one radiometer to another, because the response spectra of the radiometers vary from manufacturer to manufacturer. Broader-spectrum lights (fluorescent and halogen) have fewer variations among radiometers. Manufacturers of phototherapy systems generally recommend the specific radiometer to be used in measuring the dose of phototherapy when their system is used.

It is important also to recognize that the measured irradiance will vary widely depending on where the measurement is taken. Irradiance measured below the center of the light source can be more than double that measured at the periphery, and this dropoff at the periphery will vary with different phototherapy units. Ideally, irradiance should be measured at multiple sites under the area illuminated by the unit and the measurements averaged. The International Electrotechnical Commission³ defines the "effective surface area" as the intended treatment surface that is illuminated by the phototherapy light. The commission uses 60 × 30 cm as the standard-sized surface.

Is It Necessary to Measure Phototherapy Doses Routinely?

Although it is not necessary to measure spectral irradiance before each use of phototherapy, it is important to perform periodic checks of phototherapy units to make sure that an adequate irradiance is being delivered.

The Dose-Response Relationship of Phototherapy

Figure 5 shows that there is a direct relationship between the irradiance used and the rate at which the serum bilirubin declines under phototherapy.⁴ The data in Fig 5 suggest that there is a saturation point beyond which an increase in the irradiance produces no added efficacy. We do not know, however, that a saturation point exists. Because the conversion of bilirubin to excretable photoproducts is partly irreversible and follows first-order kinetics, there may not be a saturation point, so we do not know the maximum effective dose of phototherapy.

Effect on Irradiance of the Light Spectrum and the Distance Between the Infant and the Light Source

Figure 6 shows that as the distance between the light source and the infant decreases, there is a corresponding increase in the spectral irradiance.⁵ Fig 6 also demonstrates the dramatic difference in irradiance

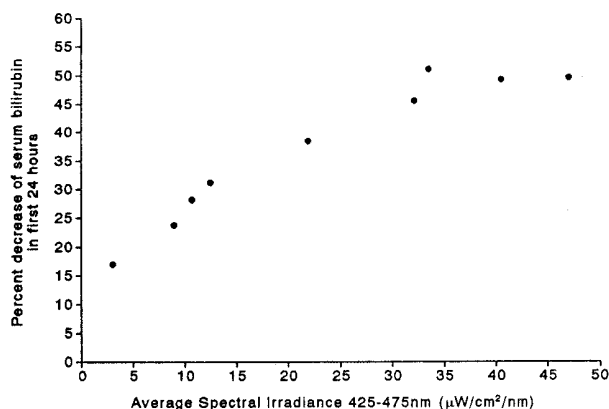


Fig 5. Relationship between average spectral irradiance and decrease in serum bilirubin concentration. Term infants with nonhemolytic hyperbilirubinemia were exposed to special blue lights (Phillips TL 52/20W) of different intensities. Spectral irradiance was measured as the average of readings at the head, trunk, and knees. Drawn from the data of Tan.⁴ Source: *Pediatrics*. 1996;98:283-287.

ance produced within the important 425- to 475-nm band by different types of fluorescent tubes.

What is Intensive Phototherapy?

Intensive phototherapy implies the use of high levels of irradiance in the 430- to 490-nm band (usually 30 $\mu\text{W}/\text{cm}^2$ per nm or higher) delivered to as much of the infant's surface area as possible. How this can be achieved is described below.

Using Phototherapy Effectively

Light Source

The spectrum of light delivered by a phototherapy unit is determined by the type of light source and

any filters used. Commonly used phototherapy units contain daylight, cool white, blue, or "special blue" fluorescent tubes. Other units use tungsten-halogen lamps in different configurations, either free-standing or as part of a radiant warming device. Recently, a system using high-intensity gallium nitride light-emitting diodes has been introduced.⁶ Fiber-optic systems deliver light from a high-intensity lamp to a fiber-optic blanket. Most of these devices deliver enough output in the blue-green region of the visible spectrum to be effective for standard phototherapy use. However, when bilirubin levels approach the range at which intensive phototherapy is recommended, maximal efficiency must be sought. The most effective light sources currently commercially available for phototherapy are those that use special blue fluorescent tubes⁷ or a specially designed light-emitting diode light (Natus Inc, San Carlos, CA).⁶ The special blue fluorescent tubes are labeled F20T12/BB (General Electric, Westinghouse, Sylvania) or TL52/20W (Phillips, Eindhoven, The Netherlands). It is important to note that special blue tubes provide much greater irradiance than regular blue tubes (labeled F20T12/B) (Fig 6). Special blue tubes are most effective because they provide light predominantly in the blue-green spectrum. At these wavelengths, light penetrates skin well and is absorbed maximally by bilirubin.⁷

There is a common misconception that ultraviolet light is used for phototherapy. The light systems used do not emit significant ultraviolet radiation, and the small amount of ultraviolet light that is emitted by fluorescent tubes and halogen bulbs is in longer wavelengths than those that cause erythema. In addition, almost all ultraviolet light is absorbed by the glass wall of the fluorescent tube and the Plexiglas cover of the phototherapy unit.

Distance From the Light

As can be seen in Fig 6, the distance of the light source from the infant has a dramatic effect on the spectral irradiance, and this effect is most significant when special blue tubes are used. To take advantage of this effect, the fluorescent tubes should be placed as close to the infant as possible. To do this, the infant should be in a bassinet, not an incubator, because the top of the incubator prevents the light from being brought sufficiently close to the infant. In a bassinet, it is possible to bring the fluorescent tubes within approximately 10 cm of the infant. Naked term infants do not become overheated under these lights. It is important to note, however, that the halogen spot phototherapy lamps cannot be positioned closer to the infant than recommended by the manufacturers without incurring the risk of a burn. When halogen lamps are used, manufacturers recommendations should be followed. The reflectors, light source, and transparent light filters (if any) should be kept clean.

Surface Area

A number of systems have been developed to provide phototherapy above and below the infant.^{8,9} One commercially available system that does this is the BiliBassinet (Olympic Medical, Seattle, WA). This

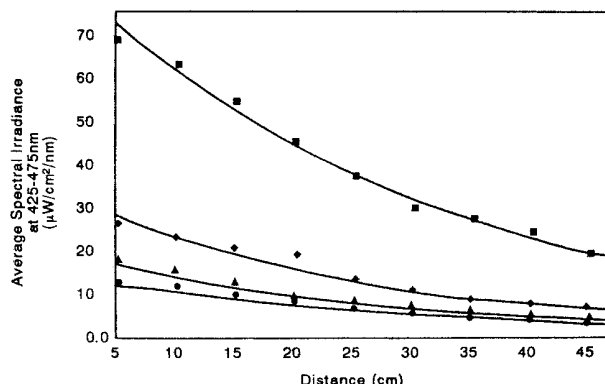


Fig 6. Effect of light source and distance from the light source to the infant on average spectral irradiance. Measurements were made across the 425- to 475-nm band by using a commercial radiometer (Olympic Bilimeter Mark II) and are the average of measurements taken at different locations at each distance (irradiance at the center of the light is much higher than at the periphery). The phototherapy unit was fitted with eight 24-in fluorescent tubes. ■ indicates special blue, General Electric 20-W F20T12/BB tube; ◆, blue, General Electric 20-W F20T12/B tube; ▲, daylight blue, 4 General Electric 20-W F20T12/B blue tubes and 4 Sylvania 20-W F20T12/D daylight tubes; •, daylight, Sylvania 20-W F20T12/D daylight tube. Curves were plotted by using linear curve fitting (True Epistat, Epistat Services, Richardson, TX). The best fit is described by the equation $y = Ae^{Bx}$. Source: *Pediatrics*. 1996;98:283-287.

unit provides special blue fluorescent tubes above and below the infant. An alternative is to place fiber-optic pads below an infant with phototherapy lamps above. One disadvantage of fiber-optic pads is that they cover a relatively small surface area so that 2 or 3 pads may be needed.⁵ When bilirubin levels are extremely high and must be lowered as rapidly as possible, it is essential to expose as much of the infant's surface area to phototherapy as possible. In these situations, additional surface-area exposure can be achieved by lining the sides of the bassinet with aluminum foil or a white cloth.¹⁰

In most circumstances, it is not necessary to remove the infant's diaper, but when bilirubin levels approach the exchange transfusion range, the diaper should be removed until there is clear evidence of a significant decline in the bilirubin level.

What Decline in the Serum Bilirubin Can You Expect?

The rate at which the bilirubin declines depends on the factors listed in Table 5, and different responses can be expected depending on the clinical circumstances. When bilirubin levels are extremely high (more than 30 mg/dL [513 μ mol/L]), and intensive phototherapy is used, a decline of as much as 10 mg/dL (171 μ mol/L) can occur within a few hours,¹¹ and a decrease of at least 0.5 to 1 mg/dL per hour can be expected in the first 4 to 8 hours.¹² On average, for infants of more than 35 weeks' gestation readmitted for phototherapy, intensive phototherapy can produce a decrement of 30% to 40% in the initial bilirubin level by 24 hours after initiation of phototherapy.¹³ The most significant decline will occur in the first 4 to 6 hours. With standard phototherapy systems, a decrease of 6% to 20% of the initial bilirubin level can be expected in the first 24 hours.^{8,14}

Intermittent Versus Continuous Phototherapy

Clinical studies comparing intermittent with continuous phototherapy have produced conflicting results.^{15–17} Because all light exposure increases bilirubin excretion (compared with darkness), no plausible scientific rationale exists for using intermittent phototherapy. In most circumstances, however, phototherapy does not need to be continuous. Phototherapy may be interrupted during feeding or brief parental visits. Individual judgment should be exercised. If the infant's bilirubin level is approaching the exchange transfusion zone (Fig 4), phototherapy should be administered continuously until a satisfactory decline in the serum bilirubin level occurs or exchange transfusion is initiated.

Hydration

There is no evidence that excessive fluid administration affects the serum bilirubin concentration. Some infants who are admitted with high bilirubin levels are also mildly dehydrated and may need supplemental fluid intake to correct their dehydration. Because these infants are almost always breastfed, the best fluid to use in these circumstances is a milk-based formula, because it inhibits the enterohepatic circulation of bilirubin and should help to lower the serum bilirubin level. Because the photo-

products responsible for the decline in serum bilirubin are excreted in urine and bile,¹⁸ maintaining adequate hydration and good urine output should help to improve the efficacy of phototherapy. Unless there is evidence of dehydration, however, routine intravenous fluid or other supplementation (eg, with dextrose water) of term and near-term infants receiving phototherapy is not necessary.

When Should Phototherapy Be Stopped?

There is no standard for discontinuing phototherapy. The TSB level for discontinuing phototherapy depends on the age at which phototherapy is initiated and the cause of the hyperbilirubinemia.¹³ For infants who are readmitted after their birth hospitalization (usually for TSB levels of 18 mg/dL [308 μ mol/L] or higher), phototherapy may be discontinued when the serum bilirubin level falls below 13 to 14 mg/dL (239–239 μ mol/L). Discharge from the hospital need not be delayed to observe the infant for rebound.^{13,19,20} If phototherapy is used for infants with hemolytic diseases or is initiated early and discontinued before the infant is 3 to 4 days old, a follow-up bilirubin measurement within 24 hours after discharge is recommended.¹³ For infants who are readmitted with hyperbilirubinemia and then discharged, significant rebound is rare, but a repeat TSB measurement or clinical follow-up 24 hours after discharge is a clinical option.¹³

Home Phototherapy

Because the devices available for home phototherapy may not provide the same degree of irradiance or surface-area exposure as those available in the hospital, home phototherapy should be used only in infants whose bilirubin levels are in the "optional phototherapy" range (Fig 3); it is not appropriate for infants with higher bilirubin concentrations. As with hospitalized infants, it is essential that serum bilirubin levels be monitored regularly.

Sunlight Exposure

In their original description of phototherapy, Cremer et al²¹ demonstrated that exposure of newborns to sunlight would lower the serum bilirubin level. Although sunlight provides sufficient irradiance in the 425- to 475-nm band to provide phototherapy, the practical difficulties involved in safely exposing a naked newborn to the sun either inside or outside (and avoiding sunburn) preclude the use of sunlight as a reliable therapeutic tool, and it therefore is not recommended.

Complications

Phototherapy has been used in millions of infants for more than 30 years, and reports of significant toxicity are exceptionally rare. Nevertheless, phototherapy in hospital separates mother and infant, and eye patching is disturbing to parents. The most important, but uncommon, clinical complication occurs in infants with cholestatic jaundice. When these infants are exposed to phototherapy, they may develop a dark, grayish-brown discoloration of the skin, serum, and urine (the bronze infant syndrome).²² The

pathogenesis of this syndrome is unknown, but it may be related to an accumulation of porphyrins and other metabolites in the plasma of infants who develop cholestasis.^{22,23} Although it occurs exclusively in infants with cholestasis, not all infants with cholestatic jaundice develop the syndrome.

This syndrome generally has had few deleterious consequences, and if there is a need for phototherapy, the presence of direct hyperbilirubinemia should not be considered a contraindication to its use. This is particularly important in sick neonates. Because the products of phototherapy are excreted in the bile, the presence of cholestasis will decrease the efficacy of phototherapy. Nevertheless, infants with direct hyperbilirubinemia often show some response to phototherapy. In infants receiving phototherapy who develop the bronze infant syndrome, exchange transfusion should be considered if the TSB is in the intensive phototherapy range and phototherapy does not promptly lower the TSB. Because of the paucity of data, firm recommendations cannot be made. Note, however, that the direct serum bilirubin should not be subtracted from the TSB concentration in making decisions about exchange transfusions (see Fig 4).

Rarely, purpura and bullous eruptions have been described in infants with severe cholestatic jaundice receiving phototherapy,^{24,25} and severe blistering and photosensitivity during phototherapy have occurred in infants with congenital erythropoietic porphyria.^{26,27} Congenital porphyria or a family history of porphyria is an absolute contraindication to the use of phototherapy, as is the concomitant use of drugs or agents that are photosensitizers.²⁸

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All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

ERRATUM

Two errors appeared in the American Academy of Pediatrics clinical practice guideline, titled "Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation," that was published in the July 2004 issue of *Pediatrics* (2004;114:297–316). On page 107, Background section, first paragraph, the second sentence should read: "The current guideline represents a consensus of the committee charged by the AAP with reviewing and updating the existing guideline and is based on a careful review of the evidence, including a comprehensive literature review by the Agency for Healthcare Research and Quality and the New England Medical Center Evidence-Based Practice Center."² On page 118, Appendix 1, first paragraph, the 4 levels of evidence quality should have been labeled A, B, C, and D rather than 1, 2, 3, and 4, respectively. The American Academy of Pediatrics regrets these errors.

**Technical Report Summary:
An Evidence-Based Review of Important Issues Concerning
Neonatal Hyperbilirubinemia**

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ABSTRACT. This article is adapted from a published evidence report concerning neonatal hyperbilirubinemia with an added section on the risk of blood exchange transfusion (BET). Based on a summary of multiple case reports that spanned more than 30 years, we conclude that kernicterus, although infrequent, has at least 10% mortality and at least 70% long-term morbidity. It is evident that the preponderance of kernicterus cases occurred in infants with a bilirubin level higher than 20 mg/dL. Given the diversity of conclusions on the relationship between peak bilirubin levels and behavioral and neurodevelopmental outcomes, it is apparent that the use of a single total serum bilirubin level to predict long-term outcomes is inadequate and will lead to conflicting results. Evidence for efficacy of treatments for neonatal hyperbilirubinemia was limited. Overall, the 4 qualifying studies showed that phototherapy had an absolute risk-reduction rate of 10% to 17% for prevention of serum bilirubin levels higher than 20 mg/dL in healthy infants with jaundice. There is no evidence to suggest that phototherapy for neonatal hyperbilirubinemia has any long-term adverse neurodevelopmental effects. Transcutaneous measurements of bilirubin have a linear correlation to total serum bilirubin and may be useful as screening devices to detect clinically significant jaundice and decrease the need for serum bilirubin determinations. Based on our review of the risks associated with BETs from 15 studies consisting mainly of infants born before 1970, we conclude that the mortality within 6 hours of BET ranged from 3 per 1000 to 4 per 1000 exchanged infants who were term and without serious hemolytic diseases. Regardless of the definitions and rates of BET-associated morbidity and the various pre-exchange clinical states of the exchanged infants, in many cases the morbidity was minor (eg, postexchange anemia). Based on the results from the most recent study to report BET morbidity, the overall risk of permanent sequelae in 25 sick infants who survived BET was from 5% to 10%.

The American Academy of Pediatrics (AAP) requested an evidence report from the Agency for Healthcare Research and Quality (AHRQ) that would critically examine the available evidence regarding the effect of high levels of bilirubin on behavioral and neurodevelopmental outcomes, role of various comorbid effect modifiers (eg, sepsis and hemolysis) on neurodevelopment, efficacy of phototherapy, reliability of various strategies in predicting significant hyperbilirubinemia, and accuracy of transcutaneous bilirubin (TcB) measurements. The report was used by the AAP to update the 1994 AAP guidelines for the management of neonatal hyperbilirubinemia. This review focuses on otherwise healthy term or near-term (at least 34 weeks' estimated gestational age [EGA] or at least 2500 g birth weight) infants with hyperbilirubinemia. This article is adapted from that published report with an added section on the risk of blood exchange transfusion (BET).

Neither hyperbilirubinemia nor kernicterus are reportable diseases, and there are no reliable sources of information providing national annual estimates. Since the advent of effective prevention of rhesus (Rh) incompatibility and treatment of elevated bilirubin levels with phototherapy, kernicterus has become uncommon. When

laboratory records of a 1995–1996 birth cohort of more than 50 000 California infants were examined, Newman et al reported that 2% had total serum bilirubin (TSB) levels higher than 20 mg/dL, 0.15% had levels higher than 25 mg/dL, and only 0.01% had levels higher than 30 mg/dL. (These data were from infants with clinically identified hyperbilirubinemia and, as such, represent a minimum estimate of the true incidence of extreme hyperbilirubinemia.) This is undoubtedly the result of successful prevention of hemolytic anemia and the application of effective treatment of elevated serum bilirubin levels in accordance with currently accepted medical practice. Projecting the California estimates to the national birth rate of 4 million per year, one can predict 80 000, 6000, and 400 newborns per year with bilirubin levels of more than 20, 25, and 30 mg/dL, respectively.

Recently, concern has been expressed that the increase in early hospital discharges, coupled with a rise in breastfeeding rates, has led to a rise in the rate of preventable kernicterus resulting from “unattended to” hyperbilirubinemia. However, a report published in 2002, based on a national registry established since 1992, reported only 90 cases of kernicterus, although the efficiency of case ascertainment is not clear. Thus, there are no data to establish incidence trends reliably for either hyperbilirubinemia or kernicterus.

Despite these constraints, there has been substantial research on the neurodevelopmental outcomes of hyperbilirubinemia and its prediction and treatment. Subsequent sections of this review describe in more detail the precise study questions and the existing published work in this area.

METHODOLOGY

This evidence report is based on a systematic review of the medical literature. Our Evidence-Based Practice Center formed a review team consisting of pediatricians and Evidence-Based Practice Center methodologic staff to review the literature and perform data abstraction and analysis. For details regarding methodology, please see the original AHRQ report.

Key Questions

Question 1: What is the relationship between peak bilirubin levels and/or duration of hyperbilirubinemia and neurodevelopmental outcome?

Question 2: What is the evidence for effect modification of the results in question 1 by GA, hemolysis, serum albumin, and other factors? Question 3: What are the quantitative estimates of efficacy of treatment for 1) reducing peak bilirubin levels (eg, number needed to treat [NNT] at 20 mg/dL to keep TSB from rising); 2) reducing the duration of hyperbilirubinemia (eg, average number of hours by which time TSB is higher than 20 mg/dL may be shortened by treatment); and 3) improving neurodevelopmental outcomes?

Question 4: What is the efficacy of various strategies for predicting hyperbilirubinemia, including hour-specific bilirubin percentiles? Question 5: What is the accuracy of TcB measurements?

Search Strategies

We searched the Medline database on September 25, 2001, for publications from 1966 to the present using relevant medical subject heading terms ("hyperbilirubinemia"; "hyperbilirubinemia, hereditary"; "bilirubin"; "jaundice, neonatal"; and "kernicterus") and text words ("bilirubin," "hyperbilirubinemia," "jaundice," "kernicterus," and "neonatal"). The abstracts were limited to human subjects and English-language studies focusing on newborns between birth and 1 month of age. In addition, the same text words used for the Medline search were used to search the Pre-Medline database. The strategy yielded 4280 Medline and 45 Pre-Medline abstracts. We consulted domain experts and examined relevant review articles for additional studies. A supplemental search for case reports of kernicterus in reference lists of relevant articles and reviews was performed also.

Screening and Selection Process

In our preliminary screening of abstracts, we identified more than 600 potentially relevant articles in total for questions 1, 2, and 3. To handle this large number of articles, we devised the following scheme to address the key questions and ensure that the report was completed within the time and resource constraints. We included only studies that measured neurodevelopmental or behavioral outcomes (except for question 3, part 1, for which we evaluated all studies addressing the efficacy of treatment). For the specific question of quantitative estimates of efficacy of treatment, all studies concerning therapies designed to prevent hyperbilirubinemia (generally bilirubin greater than or equal to 20 mg/dL) were included in the review.

Inclusion Criteria

The target population of this review was healthy, term infants. For the purpose of this review, we included articles concerning infants who were at least 34 weeks' EGA at the time of birth. From studies that reported birth weight rather than age, infants whose birth weight was greater than or equal to 2500 g were included. This cutoff was derived from findings of the National Institute of Child Health and Human Development (NICHD) hyperbilirubinemia study, in which none of the 1339 infants weighing greater than or equal to 2500 g were less than 34 weeks' EGA. Articles were selected for inclusion in the systematic review based on the following additional criteria:

Question 1 or 2 (Risk Association)

- Population: infants greater than or equal to 34 weeks' EGA or birth weight greater than or equal to 2500 g.
- Sample size: more than 5 subjects per arm
- Predictors: jaundice or hyperbilirubinemia
- Outcomes: at least 1 behavioral/neurodevelopmental outcome reported in the article
- Study design: prospective cohorts (more than 2 arms), prospective cross-sectional study, prospective longitudinal study, prospective single-arm study, or retrospective cohorts (more than 2 arms)

Case Reports of Kernicterus

- Population: kernicterus case
- Study design: case reports with kernicterus as a predictor or an outcome

Kernicterus, as defined by authors, included any of the following: acute phase of kernicterus (poor feeding, lethargy, high-pitched cry, increased tone, opisthotonos, or seizures), kernicterus sequelae (motor delay, sensorineural hearing loss, gaze palsy, dental dysplasia, cerebral palsy, or mental retardation), necropsy finding of yellow staining in the brain nuclei.

Question 3 (Efficacy of Treatment at Reducing Serum Bilirubin)

- Population: infants greater than or equal to 34 weeks' EGA or birth weight greater than or equal to 2500 g
- Sample size: more than 10 subjects per arm
- Treatments: any treatment for neonatal hyperbilirubinemia
- Outcomes: serum bilirubin level higher than or equal to 20 mg/dL or frequency of BET specifically for bilirubin level higher than or equal to 20 mg/dL
- Study design: randomized or nonrandomized, controlled trials

For All Other Issues

- Population: infants greater than or equal to 34 weeks' EGA or birth weight greater than or equal to 2500 g
- Sample size: more than 10 subjects per arm for phototherapy; any sample size for other treatments
- Treatments: any treatment for neonatal hyperbilirubinemia
- Outcomes: at least 1 neurodevelopmental outcome was reported in the article

Question 4 or 5 (Diagnosis)

- Population: infants greater than or equal to 34 weeks' EGA or birth weight greater than or equal to 2500 g
- Sample size: more than 10 subjects
- Reference standard: laboratory-based TSB

Exclusion Criteria

Case reports of kernicterus were excluded if they did not report serum bilirubin level or GA and birth weight.

Results of Screening of Titles and Abstracts

There were 158, 174, 99, 153, and 79 abstracts for questions 1, 2, 3, 4, and 5, respectively. Some articles were relevant to more than 1 question.

Results of Screening of Full-Text Articles

After full-text screening (according to the inclusion and exclusion criteria described previously), 138 retrieved articles were included in this report. There were 35 articles in the correlation section (questions 1 and 2), 28 articles of kernicterus case reports, 21 articles in the treatment section (question 3), and 54 articles in the diagnosis section (questions 4 and 5). There were inevitable overlaps, because treatment effects and assessment of neurodevelopmental outcomes were inherent in many study designs.

Reporting the Results

Articles that passed the full-text screening were grouped according to topic and analyzed in their entirety. Extracted data were synthesized into evidence tables.

Summarizing the Evidence of Individual Studies

Grading of the evidence can be useful for indicating the overall methodologic quality of a study. The evidence-grading scheme used here assesses 4 dimensions that are important for the proper interpretation of the evidence: study size, applicability, summary of results, and methodologic quality.

Definitions of Terminology

- Confounders (for question 1 only): 1) An ideal study design to answer question 1 would follow 2 groups, jaundiced and normal infants, without treating any infant for a current or consequent jaundice condition and observe their neurodevelopmental outcomes. Therefore, any treatment received by the subjects in the study was defined as a confounder. 2) If subjects had known risk factors for jaundice such as prematurity, breastfeeding, or low birth weight, the risk factors were defined as confounders. 3) Any disease condition other than jaundice was defined as a confounder. 4) Because bilirubin level is the essential predictor, if the study did not report or measure bilirubin levels for the subjects, lack of bilirubin measurements was defined as a confounder.
- Acute phase of kernicterus: poor feeding, lethargy, high-pitched cry, increased tone, opisthotonos, or seizures.
- Chronic kernicterus sequelae: motor delay, sensorineural hearing loss, gaze palsy, dental dysplasia, cerebral palsy, or mental retardation.

Statistical Analyses

In this report, 2 statistical analyses were performed in which there were sufficient data: the NNT and receiver operating characteristics (ROC) curve.

NNT

The NNT can be a clinically meaningful metric to assess the benefits of clinical trials. It is calculated by taking the inverse of the absolute risk difference. The absolute risk difference is the difference between the event rates between the treatment and control groups. For example, if the event rate is 15% in the control group and 10% in the treatment group, the absolute risk difference is 5% (an absolute risk reduction of 5%). The NNT then would be 20 (1 divided by 0.05), meaning that 20 patients will need to be treated to see 1 fewer event. In the setting of neonatal hyperbilirubinemia, NNT might be interpreted as the number of newborns needed to be treated (with phototherapy) at 13 to 15 mg/dL to prevent 1 newborn from reaching 20 mg/dL.

ROC Curve

ROC curves were developed for individual studies in question 4 if multiple thresholds of a diagnostic technology were reported. The areas under the curves (AUCs) were calculated to provide an assessment of the overall accuracy of the tests.

Meta-analyses of Diagnostic Test Performance

Meta-analyses were performed to quantify the TcB measurements for which the data were sufficient. We used 3 complementary methods for assessing diagnostic test performance: summary ROC analysis, independently combined sensitivity and specificity values, and meta-analysis of correlation coefficients.

RESULTS

Question 1. What Is the Relationship Between Peak Bilirubin Levels and/or Duration of Hyperbilirubinemia and Neurodevelopmental Outcome?

The first part of the results for this question deals with kernicterus; the second part deals with otherwise healthy term or near-term infants who had hyperbilirubinemia.

Case Reports of Kernicterus

Our literature search identified 28 case-report articles of infants with kernicterus that reported sufficient data for analysis. (The largest case series of 90 healthy term and near-term infants with kernicterus was reported by Johnson et al in 2002, but no individual data were available and therefore were not included in this analysis.

Those cases with available individual data previously reported were included in this analysis.) Most of the articles were identified in Medline and published since 1966. We retrieved additional articles published before 1966 based on review of references in articles published since 1966. Our report focuses on term and near-term infants (greater than or equal to 34 weeks' EGA). Only infants with measured peak bilirubin level and known GA or birth weight or with clinical or autopsy-diagnosed kernicterus were included in the analysis. It is important to note that some of these peak levels were obtained more than 7 days after birth and therefore may not have represented true peak levels. Similarly, some of the diagnoses of kernicterus were made only at autopsies, and the measured bilirubin levels were obtained more than 24 hours before the infants died, and therefore the reported bilirubin levels may not have reported the true peak levels. Because of the small number of subjects, none of the following comparisons are statistically significant. Furthermore, because case reports in this section represent highly selected cases, interpreting these data must be done cautiously.

Demographics of Kernicterus Cases

Articles identified through the search strategy span from 1955 to 2001 with a total of 123 cases of kernicterus. Twelve cases in 2 studies were reported before 1960; however, some studies reported cases that spanned almost 2 decades. Data on subjects' birth years were reported in only 55 cases. Feeding status, gender, racial background, and ethnicity were not noted in most of the reports. Of those that were reported, almost all the subjects were breastfed and most were males.

Geographic Distribution of Reported Kernicterus Cases

The 28 case reports with a total of 123 cases are from 14 different countries. They are the United States, Singapore, Turkey, Greece, Taiwan, Denmark, Canada, Japan, United Kingdom, France, Jamaica, Norway, Scotland, and Germany. The number of kernicterus cases in each study ranged from 1 to 12.

Kernicterus has been defined by pathologic findings, acute clinical findings, and chronic sequelae (such as deafness or athetoid cerebral palsy). Because of the small number of subjects, all definitions of kernicterus have been included in the analysis. Exceptions will be noted in the following discussion.

Kernicterus Cases With Unknown Etiology

Among infants at greater than or equal to 34 weeks' GA or who weighed 2500 g or more at birth and had no known explanation for kernicterus, there were 35 infants with peak bilirubin ranging from 22.5 to 54 mg/dL. Fifteen had no information on gender, 14 were males, and 6 were females. Fourteen had no information on feeding,

20 were breastfed, and 1 was formula-fed. More than 90% of the infants with kernicterus had bilirubin higher than 25 mg/dL: 25% of the kernicterus cases had peak TSB levels up to 29.9 mg/dL, and 50% had peak TSB levels up to 34.9 mg/dL (Fig 2). There was no association between bilirubin level and birth weight.

Four infants died. Four infants who had acute clinical kernicterus had normal follow-up at 3 to 6 years by telephone. One infant with a peak bilirubin level of 44 mg/dL had a flat brainstem auditory evoked response (BAER) initially but normalized at 2 months of age; this infant had normal neurologic and developmental examinations at 6 months of age. Ten infants had chronic sequelae of kernicterus when followed up between 6 months and 7 years of age. Seven infants were noted to have neurologic findings consistent with kernicterus; however, the age at diagnosis was not provided. Nine infants had a diagnosis of kernicterus with no follow-up information provided. To summarize, 11% of this group of infants died, 14% survived with no sequelae, and at least 46% had chronic sequelae. The distribution of peak TSB levels was higher when only infants who died or had chronic sequelae were included.

Kernicterus Cases With Comorbid Factors

In the 88 term and near-term infants diagnosed with kernicterus and who had hemolysis, sepsis, and other neonatal complications, bilirubin levels ranged from 4.0 to 51.0 mg/dL (as previously mentioned, these may not represent true peak levels; the bilirubin level of 4 mg/dL was measured more than 24 hours before the infant died, the diagnosis of kernicterus was made by autopsy). Forty-two cases provided no information on gender, 25 were males, and 21 were females. Seventy-two cases had no information on feeding, 15 were breastfed, and 1 was formula-fed. Most infants with kernicterus had bilirubin levels higher than 20 mg/dL: 25% of the kernicterus cases had peak TSB levels up to 24.9 mg/dL, and 50% had peak TSB levels up to 29.9 mg/dL (Fig 4). In this group, there was no association between the bilirubin levels and birth weight.

Five infants without clinical signs of kernicterus were diagnosed with kernicterus by autopsy. Eight infants died of kernicterus. One infant was found to have a normal neurologic examination at 4 months of age. Another infant with galactosemia and a bilirubin level of 43.6 mg/dL who had acute kernicterus was normal at 5 months of age. Forty-nine patients had chronic sequelae ranging from hearing loss to athetoid cerebral palsy; the follow-up age reported ranged from 4 months to 14 years. Twenty-one patients were diagnosed with kernicterus, with no follow-up information. Not including the autopsy-diagnosed kernicterus, 10% of these infants died (8/82), 2% were found to be normal at 4 to 5 months of age, and

at least 60% had chronic sequelae. The distribution of peak TSB levels was slightly higher when only infants who died or had chronic sequelae were included.

Evidence Associating Bilirubin Exposures With Neurodevelopmental Outcomes in Healthy Term or Near-Term Infants

This section examines the evidence associating bilirubin exposures with neurodevelopmental outcomes primarily in subjects without kernicterus. Studies that were designed specifically to address the behavioral and neurodevelopmental outcomes in healthy infants at more than or equal to 34 weeks' GA will be discussed first. With the exception of the results from the Collaborative Perinatal Project (CPP) (CPP, with 54 795 subjects, has generated many follow-up studies with a smaller number of subjects, and those studies were discussed together in a separate section in the AHRQ summary report), the remainder of the studies that include mixed subjects (preterm and term, diseased and nondiseased) were categorized and discussed by outcome measures. These measures include behavioral and neurologic outcomes; hearing impairment, including sensorineural hearing loss; and intelligence measurements.

The CPP, with 54 795 live births between 1959 and 1966 from 12 centers in the United States, produced the largest database for the study of hyperbilirubinemia. Newman and Klebanoff, focusing only on black and white infants weighing 2500 g or more at birth, did a comprehensive analysis of 7-year outcome in 33 272 subjects. All causes of jaundice were included in the analysis. The study found no consistent association between peak bilirubin level and intelligence quotient (IQ). Sensorineural hearing loss was not related to bilirubin level. Only the frequency of abnormal or suspicious neurologic examinations was associated with bilirubin level. The specific neurologic examination items most associated with bilirubin levels were mild and nonspecific motor abnormalities.

In other studies stemming from the CPP population, there was no consistent evidence to suggest neurologic abnormalities in children with neonatal bilirubin higher than 20 mg/dL when followed up to 7 years of age.

A question that has concerned pediatricians for many years is whether moderate hyperbilirubinemia is associated with abnormalities in neurodevelopmental outcome in term healthy infants without perinatal or neonatal problems. Only 4 prospective studies and 1 retrospective study have the requisite subject characteristics to address this issue. Although there were some short-term (less than 12 months) abnormal neurologic or behavioral characteristics noted in infants with high bilirubin, the studies had methodologic problems and did not show consistent results.

Evidence Associating Bilirubin Exposures With Neurodevelopmental Outcomes in All Infants

These studies consist of subjects who, in addition to healthy term newborns, might include newborns less than 34 weeks' GA and neonatal complications such as sepsis, respiratory distress, hemolytic disorders, and other factors. Nevertheless, some of the conclusions drawn might be applicable to a healthy term population. In these studies, greater emphasis will be placed on the reported results for the group of infants who were at greater than or equal to 34 weeks' EGA or weighed 2500 g or more at birth.

Studies Measuring Behavioral and Neurologic Outcomes in Infants With Hyperbilirubinemia

A total of 9 studies in 11 publications examined primarily behavioral and neurologic outcomes in patients with hyperbilirubinemia. Of these 9 studies, 3 were of high methodologic quality. One short-term study showed a correlation between bilirubin level and decreased scores on newborn behavioral measurements. One study found no difference in prevalence of central nervous system abnormalities at 4 years old if bilirubin levels were less than 20 mg/dL, but infants with bilirubin levels higher than 20 mg/dL had a higher prevalence of central nervous system abnormalities. Another study that followed infants with bilirubin levels higher than 16 mg/dL found no relationship between bilirubin and neurovisuomotor testing at 61 to 82 months of age. Although data reported in the remainder of the studies are of lower methodologic quality, there is a suggestion of abnormalities in neurodevelopmental screening tests in infants with bilirubin levels higher than 20 mg/dL, at least by the Denver Developmental Screening Test, when infants were followed up at 1 year of age. It seems that bilirubin levels higher than 20 mg/dL may have short-term (up to 1 year of age) adverse effects at least by the Denver Developmental Screening Test, but there is no strong evidence to suggest neurologic abnormalities in children with neonatal bilirubin levels higher than 20 mg/dL when followed up to 7 years of age.

Effect of Bilirubin on Brainstem Auditory Evoked Potential (BAEP)

The following group of studies, in 14 publications, primarily examined the effect of bilirubin on BAEP or hearing impairment. Eight high-quality studies showed a significant relationship between abnormalities in BAEP and high bilirubin levels. Most reported resolution of abnormalities with treatment. Three studies reported hearing impairment associated with elevated bilirubin (higher than 16–20 mg/dL).

Effect of Bilirubin on Intelligence Outcomes

Eight studies looked primarily at the effect of bilirubin on intelligence outcomes. Four high-quality studies with

follow-up ranging from 6.5 to 17 years reported no asso-

ciation between IQ and bilirubin level.

Question 2. What Is the Evidence for Effect Modification of the Results in Question 1 by GA, Hemolysis, Serum Albumin, and Other Factors?

There is only 1 article that directly addressed this question. Naeye, using the CPP population, found that at 4 years old the frequency of low IQ with increasing bilirubin levels increased more rapidly in infants with infected amniotic fluid. At 7 years old, neurologic abnormalities also were more prevalent in that subgroup of infants.

When comparing the group of term and near-term infants with comorbid factors who had kernicterus to the group of infants with idiopathic hyperbilirubinemia and kernicterus, the overall mean bilirubin was 31.6 ± 9 mg/dL in the former, versus 35.4 ± 8 mg/dL in the latter (difference not significant). Infants with glucose-6-phosphate dehydrogenase deficiency, sepsis, ABO incompatibility, or Rh incompatibility had similar mean bilirubin levels. Infants with more than 1 comorbid factor had a slightly lower mean bilirubin level of 29.1 ± 16.1 mg/dL.

Eighteen of 23 (78%) term infants with idiopathic hyperbilirubinemia and who developed acute kernicterus survived the neonatal period with chronic sequelae. Thirty-nine of 41 (95%) term infants with kernicterus and ABO or Rh incompatibility had chronic sequelae. Four of 5 (80%) infants with sepsis and kernicterus had chronic sequelae. All 4 infants with multiple comorbid factors had sequelae.

No firm conclusions can be drawn regarding co-morbid factors and kernicterus, because this is a small number of patients from a variety of case reports.

There was no direct study concerning serum albumin level as an effect modifier of neurodevelopmental outcome in infants with hyperbilirubinemia. One report found a significant association between reserve albumin concentration and latency to wave V in BAEP studies.

In addition, Ozmert et al noted that exchange transfusion and the duration that the infant's serum indirect bilirubin level remained higher than 20 mg/dL were important risk factors for prominent neurologic abnormalities.

Question 3. What Are the Quantitative Estimates of Efficacy of Treatment at 1) Reducing Peak Bilirubin Levels (eg, NNT at 20 mg/dL to Keep TSB From Rising); 2) Reducing the Duration of Hyperbilirubinemia (eg, Average Number of Hours by Which Time TSB Levels Higher Than 20 mg/dL May Be Shortened by Treatment); and 3) Improving Neurodevelopmental Outcomes?

Studies on phototherapy efficacy in terms of preventing TSB rising to the level that would require BET (and therefore would be considered "failure of phototherapy") were reviewed for the quantitative estimates of efficacy of phototherapy. Because trials evaluating the efficacy of phototherapy at improving neurodevelopmental outcomes by comparing 1 group of infants with treatment to an

untreated group do not exist, the effects of treatment on neurodevelopmental outcomes could only be reviewed descriptively. Furthermore, all the reports primarily examined the efficacy of treatment at 15 mg/dL to prevent TSB from exceeding 20 mg/dL. There is no study to examine the efficacy of treatment at 20 mg/dL to prevent the TSB from rising.

Efficacy of Phototherapy for Prevention of TSB Levels Higher Than 20 mg/dL

Four publications examined the clinical efficacy of phototherapy for prevention of TSB levels higher than 20 mg/dL.

Two studies evaluated the same sample of infants. Both reports were derived from a randomized, controlled trial of phototherapy for neonatal hyperbilirubinemia commissioned by the NICHD between 1974 and 1976.

Because the phototherapy protocols differed significantly in the remaining studies, their results could not be statistically combined and are reported here separately. A total of 893 term or near-term jaundiced infants (325 in the treatment group and 568 in the control group) were evaluated in the current review.

The development, design, and sample composition of NICHD phototherapy trial were reported in detail elsewhere. The NICHD controlled trial of phototherapy for neonatal hyperbilirubinemia consisted of 672 infants who received phototherapy and 667 control infants. Brown et al evaluated the efficacy of phototherapy for prevention of the need for BET in the NICHD study population. For the purpose of current review, only the subgroup of 140 infants in the treatment groups and 136 in the control groups with birth weights 2500 g or more and greater than or equal to 34 weeks' GA were evaluated. The serum bilirubin level as criterion for BET in infants with birth weights of 2500 g or more was 20 mg/dL at standard risk and 18 mg/dL at high risk. It was found that infants with hyperbilirubinemia secondary to nonhemolytic causes who received phototherapy had a 14.3% risk reduction of BET than infants in no treatment group. NNT for prevention of the need for BET or for TSB levels higher than 20 mg/dL was 7 (95% confidence interval [CI]: 6–8). However, phototherapy did not reduce the need for BET for infants with hemolytic diseases or in the high-risk group. No therapeutic effect on reducing the BET rate in infants at greater than or equal to 34 weeks' GA with hemolytic disease was observed.

The same group of infants, 140 subjects in the treatment group and 136 controls with birth weights 2500 g or more and greater than or equal to 34 weeks' GA, were evaluated for the effect of phototherapy on the hyperbilirubinemia of Coombs' positive hemolytic disease in the study of Maurer et al. Of the 276 infants whose birth weights were 2500 g or more, 64 (23%) had positive Coombs' tests: 58 secondary to ABO incompatibility and 6 secondary to Rh incom-

patibility. Thirty-four of 64 in this group received phototherapy. The other 30 were placed in the control group. Of the 212 subjects who had negative Coombs' tests, 106 were in the treatment group and the same number was in the control group. No therapeutic effect on reducing the BET rate was observed in infants with Coombs' positive hemolytic disease, but there was a 9.4% absolute risk reduction in infants who had negative Coombs' tests. In this group of infants, the NNT for prevention of the need for BET, or a TSB higher than 20 mg/dL, was 11 (95% CI: 10–12).

A more recent randomized, controlled trial compared the effect of 4 different interventions on hyperbilirubinemia (serum bilirubin concentration greater than or equal to 291 $\mu\text{mol/L}$ or 17 mg/dL) in 125 term breastfed infants. Infants with any congenital anomalies, neonatal complications, hematocrit more than 65%, significant bruising or large cephalohematomas, or hemolytic disease were excluded. The 4 interventions in the study were 1) continue breastfeeding and observe ($N = 25$); 2) discontinue breastfeeding and substitute formula ($N = 26$); 3) discontinue breastfeeding, substitute formula, and administer phototherapy ($N = 38$); and 4) continue breastfeeding and administer phototherapy ($N = 36$). The interventions were considered failures if serum bilirubin levels reached 324 $\mu\text{mol/L}$ or 20 mg/dL. For the purpose of the current review, we regrouped the subjects into treatment group or phototherapy group and control group or no-phototherapy group. Therefore, the original groups 4 and 3 became the treatment groups I and II, and the original groups 1 and 2 were the corresponding control groups I and II. It was found that treatment I, phototherapy with continuation of breastfeeding, had a 10% absolute risk-reduction rate, and the NNT for prevention of a serum bilirubin level higher than 20 mg/dL was 10 (95% CI: 9–12). Compared with treatment I, treatment II (phototherapy with discontinuation of breastfeeding) was significantly more efficacious. The absolute risk-reduction rate was 17%, and the NNT for prevention of a serum bilirubin level exceeding 20 mg/dL was 6 (95% CI: 5–7).

John reported the effect of phototherapy in 492 term neonates born during 1971 and 1972 who developed unexplained jaundice with bilirubin levels higher than 15 mg/dL. One hundred eleven infants received phototherapy, and 381 did not. The author stated: "The choice of therapy was, in effect, random since two pediatricians approved of the treatment and two did not." The results showed that phototherapy had an 11% risk reduction of BET, performed in treatment and control groups when serum bilirubin levels exceeded 20 mg/dL. Therefore, the NNT for prevention of a serum bilirubin level higher than 20 mg/dL was 9 (95% CI: 8–10).

Regardless of different protocols for phototherapy, the NNT for prevention of serum bilirubin levels higher than 20 mg/dL ranged from 6 to 10 in healthy term or near-term infants. Evidence for the efficacy of treatments

for neonatal hyperbilirubinemia was limited. Overall, the 4 qualifying studies showed that phototherapy had an absolute risk-reduction rate of 10% to 17% for prevention of serum bilirubin exceeding 20 mg/dL in healthy and jaundiced infants (TSB levels higher than or equal to 13 mg/dL) born at greater than or equal to 34 weeks' GA. Phototherapy combined with cessation of breastfeeding and substitution with formula was found to be the most efficient treatment protocol for healthy term or near-term infants with jaundice.

Effectiveness of Reduction in Bilirubin Level on BAER in Jaundiced Infants With Greater Than or Equal to 34 Weeks' EGA

Eight studies that compared BAER before and after treatments for neonatal hyperbilirubinemia are discussed in this section. Of the 8 studies, 3 studies treated jaundiced infants by administering phototherapy followed by BET according to different guidelines, 4 studies treated jaundiced infants with BET only, and 1 study did not specify what treatments jaundiced infants received. All the studies consistently showed that treatments for neonatal hyperbilirubinemia significantly improved abnormal BAERs in healthy jaundiced infants and jaundiced infants with hemolytic disease.

Effect of Phototherapy on Behavioral and Neurologic Outcomes and IQ

Five studies looked at the effect of hyperbilirubinemia and phototherapy on behavior. Of the 5 studies, 4 used the Brazelton Neonatal Behavioral Assessment Scale and 1 used the Vineland Social Maturity Scale. Three studies reported lower scores in the orientation cluster of the Brazelton Neonatal Behavioral Assessment Scale in the infants treated with phototherapy. The other 2 studies did not find behavioral changes in the phototherapy group. One study evaluated IQ at the age of 17 years. In 42 term infants with severe hyperbilirubinemia who were treated with phototherapy, 31 were also treated with BET. Forty-two infants who did not receive phototherapy were selected as controls. No significant difference in IQ between the 2 groups was found.

Effect of Phototherapy on Visual Outcomes

Three studies were identified that studied the effect of serum bilirubin and treatment on visual outcomes. All showed no short-or long-term (up to 36 months) effect on vision as a result of phototherapy when infants' eyes are protected properly during treatment.

Question 4. What Is the Accuracy of Various Strategies for Predicting Hyperbilirubinemia, Including Hour-Specific Bilirubin Percentiles?

Ten qualifying studies published from 1977 to 2001 examining 5 prediction methods of neonatal hyperbilirubinemia were included. A total of 8167 neonates, most healthy near-term or term infants, were subjects. These studies were conducted among multiple racial groups in multiple countries including China, Denmark, India, Israel, Japan, Spain, and the United States. Some studies included subjects with ABO incompatibility, and some did not. Four studies examined the accuracy of cord bilirubin level as a test for predicting the development of clinically significant neonatal jaundice. Four studies investigated the test performance of serum bilirubin levels before 48 hours of life to predict hyperbilirubinemia. Two studies further compared the test performances of cord bilirubin with that of early serum bilirubin levels. The accuracy of end-tidal carbon monoxide concentration as a predictor of the development of hyperbilirubinemia was examined in Okuyama et al and Stevenson et al. The study by Stevenson et al also examined the test performance of a combined strategy of end-tidal carbon monoxide concentration and early serum bilirubin levels. Finally, 2 studies tested the efficacy of predischarge risk assessment, determined by a risk index model and hour-specific bilirubin percentile, respectively, for predicting neonatal hyperbilirubinemia.

ROC curves were developed for 3 of the predictive strategies. The AUCs were calculated to provide an assessment of the overall accuracy of the tests. Hour-specific bilirubin percentiles had an AUC of 0.93, cord bilirubin levels had an AUC of 0.74, and predischarge risk index had an AUC of 0.80. These numbers should not be compared directly with each other, because the studies had different population characteristics and different defining parameters for hyperbilirubinemia.

Question 5. What Is the Accuracy of TcB Measurements?

A total of 47 qualifying studies in 50 publications examining the test performance of TcB measurements and/or the correlation of TcB measurements to serum bilirubin levels was reviewed in this section. Of the 47 studies, the Minolta Air-Shields jaundice meter (Air-Shields, Hatboro, PA) was used in 41 studies, the BiliCheck (SpectRx Inc, Norcross, GA) was used in 3 studies, the Ingram icterometer (Thomas A. Ingram and Co, Birmingham, England; distributed in the United States by Cascade Health Care Products, Salem, OR) was used in 4 studies, and the ColorMate III (Chromatics Color Sciences International Inc, New York, NY) was used in 1 study.

Based on the evidence from the systematic review, TcB measurements by each of the 4 devices described in the literature (the Minolta Air-Shields jaundice meter, Ingram icterometer, BiliCheck, and Chromatics ColorMate

III) have a linear correlation to TSB and may be useful as screening devices to detect clinically significant jaundice and decrease the need for serum bilirubin determinations.

Minolta Air-Shields Jaundice Meter

Generally, TcB readings from the forehead or sternum have correlated well with TSB but with a wide range of correlation coefficients, from a low of 0.52 for subgroup of infants less than 37 weeks' GA to as high as 0.96. Comparison of correlations across studies is difficult because of differences in study design and selection procedures. TcB indices that correspond to various TSB levels vary from institution to institution but seem to be internally consistent. Different TSB threshold levels were used across studies; therefore, there is limited ability to combine data across the studies. Most of the studies used TcB measurements taken at the forehead, several studies used multiple sites and combined results, 1 study used only the midsternum site, and 3 studies took the TcB measurement at multiple sites.

The Minolta Air-Shields jaundice meter seems to perform less well in black infants, compared with white infants, performs best when measurements are made at the sternum, and performs less well when infants have been exposed to phototherapy. This instrument requires daily calibration, and each institution must develop its own correlation curves of TcB to TSB. Eleven studies of the test performance of the Minolta Air-Shields jaundice meter measuring at forehead to predict a serum bilirubin threshold of higher than or equal to 13 mg/dL were included in the following analysis. A total of 1560 paired TcB and serum bilirubin measurements were evaluated. The cutoff points of Minolta Air-Shields TcB measurements (TcB index) ranged from 13 to 24 for predicting a serum bilirubin level higher than or equal to 13 mg/dL. As a screening test, it does not perform consistently across studies, as evidenced by the heterogeneity in the summary ROC curves not explained by threshold effect. The overall unweighted pooled estimates of sensitivity and specificity were 0.85 (0.77–0.91) and 0.77 (0.66–0.85).

Ingram Icterometer

The Ingram icterometer consists of a strip of transparent Plexiglas on which 5 yellow transverse stripes of precise and graded hue are painted. The correlation coefficients (r) in the 4 studies ranged from 0.63 to 0.97. The icterometer has the added limitation of lacking the objectivity of the other methods, because it depends on observer visualization of depth of yellow color of the skin.

BiliCheck

The recently introduced BiliCheck device, which uses reflectance data from multiple wavelengths, seems to be a significant improvement over the older devices (the Ingram icterometer and the Minolta Air-Shields jaundice meter) because of its ability to determine correction factors

for the effect of melanin and hemoglobin. Three studies examined the accuracy of the BiliCheck TcB measurements to predict TSB ("gold standard"). All studies were rated as high quality. The correlation coefficient ranged from 0.83 to 0.91. In 1 study, the BiliCheck was shown to be as accurate as the laboratory measurement of TSB when compared with the reference gold-standard high-performance liquid chromatography (HPLC) measurement of TSB. Analysis of covariance found no differences in test performance by postnatal age, GA, birth weight, or race; however, 66.7% were white and only 4.3% were black.

Chromatics ColorMate III

One study that evaluated the performance of the ColorMate III transcutaneous bilirubinometer was reviewed. The correlation coefficient for the whole study group was 0.9563, and accuracy was not affected by race, weight, or phototherapy. The accuracy of the device is increased by the determination of an infant's underlying skin type before the onset of visual jaundice; thus, a drawback to the method when used as a screening device is that all infants would require an initial baseline measurement.

CONCLUSIONS AND DISCUSSION

Summarizing case reports of kernicterus from different investigators in different countries from different periods is problematic. First, definitions of kernicterus used in these reports varied greatly. They included gross yellow staining of the brain, microscopic neuronal degeneration, acute clinical neuromotor impairment, neuroauditory impairment, and chronic neuromotor impairment. In some cases, the diagnoses were not established until months or years after birth. Second, case reports without controls makes interpretation difficult, especially in infants with comorbid factors, and could very well lead to misinterpretation of the role of bilirubin in neurodevelopmental outcomes. Third, different reports used different outcome measures. "Normal at follow-up" may be based on parental reporting, physician assessment, or formal neuropsychologic testing. Fourth, time of reported follow-up ranged from days to years. Fifth, cases were reported from different countries at different periods and with different standards of practice managing hyperbilirubinemia. Some countries have a high prevalence of glucose-6-phosphate dehydrogenase deficiency. Some have cultural practices that predispose their infants to agents that cause hyperbilirubinemia (such as clothing stored in dressers with naphthalene moth balls). The effect of the differences on outcomes cannot be known for certain. Finally, it is difficult to infer from case reports the true incidence of this uncommon disorder.

To recap our findings, based on a summary of multiple case reports that spanned more than 30 years, we conclude that kernicterus, although infrequent, has significant mortality (at least 10%) and long-term morbidity (at least

70%). It is evident that the preponderance of kernicterus cases occurred in infants with high bilirubin (more than 20 mg/dL).

Of 26 (19%) term or near-term infants with acute manifestations of kernicterus and reported follow-up data, 5 survived without sequelae, whereas only 3 of 63 (5%) infants with acute kernicterus and comorbid factors were reported to be normal at follow-up. This result suggests the importance of comorbid factors in determining long-term outcome in infants initially diagnosed with kernicterus.

For future research, reaching a national consensus in defining this entity, as in the model suggested by Johnson et al, will help in formulating a valid comparison of different databases. It is also apparent that, without good prevalence and incidence data on hyperbilirubinemia and kernicterus, one would not be able to estimate the risk of kernicterus at a given bilirubin level. Making severe hyperbilirubinemia (eg, greater than or equal to 25 mg/dL) and kernicterus reportable conditions would be a first step in that direction. Also, because kernicterus is infrequent, doing a multicenter case-control study with kernicterus may help to delineate the role of bilirubin in the development of kernicterus.

Hyperbilirubinemia, in most cases, is a necessary but not sufficient condition to explain kernicterus. Factors acting in concert with bilirubin must be studied to seek a satisfactory explanation. Information from duration of exposure to bilirubin and albumin binding of bilirubin may yield a more useful profile of the risk of kernicterus.

Only a few prospective controlled studies looked specifically at behavioral and neurodevelopmental outcomes in healthy term infants with hyperbilirubinemia. Most of these studies have a small number of subjects. Two short-term studies with well-defined measurement of newborn behavioral organization and physiologic measurement of cry are of high methodologic quality; however, the significance of long-term abnormalities in newborn behavior scales and variations in cry formant frequencies are unknown. There remains little information on the long-term effects of hyperbilirubinemia in healthy term infants.

Among the mixed studies (combined term and preterm, nonhemolytic and hemolytic, nondiseased and diseased), the following observations can be made:

- Nine of 15 studies (excluding the CPP) addressing neuroauditory development and bilirubin level were of high quality. Six of them showed BAER abnormalities correlated with high bilirubin levels. Most reported resolution with treatment. Three studies reported hearing impairment associated with elevated bilirubin (more than 16 to more than 20 mg/dL). We conclude that a high bilirubin level does have an adverse effect on neuroauditory function, but the adverse effect on BAER is reversible.
- Of the 8 studies reporting intelligence outcomes in

subjects with hyperbilirubinemia, 4 studies were considered high quality. These 4 studies reported no association between IQ and bilirubin level, with follow-up ranging from 6.5 to 17 years. We conclude that there is no evidence to suggest a linear association of bilirubin level and IQ.

- The analysis of the CPP population found no consistent association between peak bilirubin level and IQ. Sensorineural hearing loss was not related to bilirubin level. Only the frequency of abnormal or suspicious neurologic examinations was associated with bilirubin level. In the rest of the studies from the CPP population, there was no consistent evidence to suggest neurologic abnormalities in children with neonatal bilirubin levels more than 20 mg/dL when followed up to 7 years of age.

A large prospective study comprising healthy infants greater than or equal to 34 weeks' GA with hyperbilirubinemia, specifically looking at long-term neurodevelopmental outcomes, has yet to be done. The report of Newman and Klebanoff came closest to that ideal because of the large number of subjects and the study's analytic approach. However, a population born from 1959 to 1966 is no longer representative of present-day newborns: 1) there is now increased ethnic diversity in our newborn population; 2) breast milk jaundice has become more common than hemolytic jaundice; 3) phototherapy for hyperbilirubinemia has become standard therapy; and 4) hospital stays are shorter. These changes in biologic, cultural, and health care characteristics make it difficult to apply the conclusions from the CPP population to present-day newborns.

Although short-term studies, in general, have good methodologic quality, they use tools that have unknown long-term predictive abilities. Long-term studies suffer from high attrition rates of the study population and a nonuniform approach to defining "normal neurodevelopmental outcomes." The total bilirubin levels reported in all the studies mentioned were measured anywhere from the first day of life to more than 2 weeks of life. Definitions of significant hyperbilirubinemia ranged from greater than or equal to 12 mg/dL to greater than or equal to 20 mg/dL.

Given the diversity of conclusions reported, except in cases of kernicterus with sequelae, it is evident that the use of a single TSB level (within the range described in this review) to predict long-term behavioral or neurodevelopmental outcomes is inadequate and will lead to conflicting results.

Evidence for the efficacy of treatments for neonatal hyperbilirubinemia was limited. Overall, the 4 qualifying studies showed that phototherapy had an absolute risk-reduction rate of 10% to 17% for prevention of serum bilirubin exceeding 20 mg/dL in healthy jaundiced infants

(TSB higher than or equal to 13 mg/dL) of greater than or equal to 34 weeks' GA. Phototherapy combined with cessation of breastfeeding and substitution with formula was found to be the most efficient treatment protocol for healthy term or near-term infants with jaundice. There is no evidence to suggest that phototherapy for neonatal hyperbilirubinemia has any long-term adverse neurodevelopmental effects in either healthy jaundiced infants or infants with hemolytic disease. It is also noted that in all the studies listed, none of the infants received what is currently known as "intensive phototherapy." Although phototherapy did not reduce the need for BET in infants with hemolytic disease in the NICHD phototherapy trial, it could be attributable to the low dose of phototherapy used. Proper application of "intensive phototherapy" should decrease the need for BET further.

It is difficult to draw conclusions regarding the accuracy of various strategies for prediction of neonatal hyperbilirubinemia. The first challenge is the lack of consistency in defining clinically significant neonatal hyperbilirubinemia. Not only did multiple studies use different levels of TSB to define neonatal hyperbilirubinemia, but the levels of TSB defined as significant also varied by age, but age at TSB determination varied by study as well. For example, significant levels of TSB were defined as more than 11.7, more than or equal to 15, more than 15, more than 16, more than 17, and more than or equal to 25 mg/dL.

A second challenge is the heterogeneity of the study populations. The studies were conducted in many racial groups in different countries including China, Denmark, India, Israel, Japan, Spain, and the United States. Although infants were defined as healthy term and near-term newborns, these studies included neonates with potential for hemolysis from ABO-incompatible pregnancies as well as breastfed and bottle-fed infants (often not specified). Therefore, it is not possible to directly compare the different predicting strategies. However, all the strategies provided strong evidence that early jaundice predicts late jaundice.

Hour-specific bilirubin percentiles had an AUC of 0.93, implying great accuracy of this strategy. In that study, 2976 of 13 003 eligible infants had a postdischarge TSB measurement, as discussed by Maisels and Newman. Because of the large number of infants who did not have a postdischarge TSB, the actual study sample would be deficient in study participants with low predischarge bilirubin levels, leading to false high-sensitivity estimates and false low-specificity estimates. Moreover, the population in the study is not representative of the entire US population. The strategy of using early hour-specific bilirubin percentiles to predict late jaundice looks promising, but a large multicenter study (with evaluation of potential differences by race and ethnicity as well as prenatal, natal, and postnatal factors) may need to be undertaken to produce more applicable data.

TcB measurements by each of the 3 devices described in the literature, the Minolta Air-Shields jaundice meter, the Ingram icterometer, and the Bili-Check, have a linear correlation to TSB and may be useful as screening devices to detect clinically significant jaundice and decrease the need for serum bilirubin determinations.

The recently introduced BiliCheck device, which uses reflectance data from multiple wavelengths, seems to be a significant improvement over the older devices (the Ingram icterometer and the Minolta Air-Shields jaundice meter) because of its ability to determine correction factors for the effect of melanin and hemoglobin. In 1 study, the BiliCheck was shown to be as accurate as laboratory measures of TSB when compared with the reference gold-standard HPLC measurement of TSB.

Future research should confirm these findings in larger samples of diverse populations and address issues that might affect performance, such as race, GA, age at measurement, phototherapy, sunlight exposure, feeding and accuracy as screening instruments, performance at higher levels of bilirubin, and ongoing monitoring of jaundice. Additionally, studies should address cost-effectiveness and reproducibility in actual clinical practice. Given the interlaboratory variability of measurements of TSB, future studies of noninvasive measures of bilirubin should use HPLC and routine laboratory methods of TSB as reference standards, because the transcutaneous measures may prove to be as accurate as the laboratory measurement when compared with HPLC as the gold standard.

Using correlation coefficients to determine the accuracy of TcB measurements should be interpreted carefully because of several limitations:

- The correlation coefficient does not provide any information about the clinical utility of the diagnostic test.
- Although correlation coefficients measure the association between TcB and "standard" serum bilirubin measurements, the correlation coefficient is highly dependent on the distribution of serum bilirubin in the study population selected.
- Correlation measures ignore bias and measure relative rather than absolute agreement.

ADDENDUM: THE RISK OF BET

At the suggestion of AAP technical experts, a review of the risks associated with BET was also undertaken after the original AHRQ report was published. Articles were obtained from an informal survey of studies published since 1960 dealing with large populations that permitted calculations of the risks of morbidity and mortality. Of 15 studies, 8 consisted of subjects born before 1970. One article published in 1997 consisted of subjects born in 1994 and 1995.

Fifteen studies that reported data on BET-related mortality and/or morbidity were included in this review. Three categories were created to describe the percentage

of subjects who met the criteria of the target population of our evidence report (ie, term idiopathic jaundice infants). Category I indicates that more than 50% of the study subjects were term infants whose pre-exchange clinical state was vigorous or stable and without disease conditions other than jaundice. Category II indicates that between 10% and 50% of the study subjects had category I characteristics. Category III indicates that more than 90% of the study subjects were preterm infants and/or term infants whose pre-exchange clinical state was not stable or was critically ill and with other disease conditions.

BET Subject and Study Characteristics

Because BET is no longer the mainstay of treatment for hyperbilirubinemia, most infants who underwent BETs were born in the 1950s to 1970s. Two recent studies reported BET-related mortality and morbidity for infants born from 1981 to 1995. After 1970, there were more infants who were premature, low birth weight or very low birth weight, and/or had a clinical condition(s) other than jaundice who received BETs than those born in earlier years. Not all infants in this review received BETs for hyperbilirubinemia. Because of limited data on subjects' bilirubin levels when the BETs were performed, we could not exclude those nonjaundiced infants.

BET-Associated Mortality

For all infants, the reported BET-related mortality ranged from 0% to 7%. There were no consistent definitions for BET-related mortality in the studies. An infant who died within 6 hours after the BET was the first used to define a BET-related death by Boggs and Westphal in 1960. Including the study from Boggs and Westphal, there were 3 studies reporting the 6-hour mortality, and they ranged from 0% to 1.9%. It is difficult to isolate BET as the sole factor in explaining mortality, because most of the subjects have significant associated pre-exchange disease morbidities. Most of the infants who died from BET had blood incompatibility and sepsis or were premature, had kernicterus, and/or were critically ill before undergoing BET. When only term infants were counted, the 6-hour mortality ranged from 3 to 19 per 1000 exchanged. When those term infants with serious hemolytic diseases (such as Rh incompatibility) were excluded, the 6-hour mortality ranged from 3 to 4 per 1000 exchanged infants. All these infants were born before 1970, and their jaundice was primarily due to ABO incompatibility.

BET-Associated Morbidity

There is an extensive list of complications that have been associated with BETs. Complications include those related to the use of blood products (infection, hemolysis of transfused blood, thromboembolization, graft versus host reactions), metabolic derangements (acidosis and perturbation

of the serum concentrations of potassium, sodium, glucose, and calcium), cardiorespiratory reactions (including arrhythmias, apnea, and cardiac arrest), complications related to umbilical venous and arterial catheterization, and other miscellaneous complications. As noted previously, the pre-exchange clinical state of the infants studied varied widely, as did the definitions and rates of BET-associated morbidity. In many cases, however, the morbidity was minor (eg, postexchange anemia).

In the NICHD cooperative phototherapy study, morbidity (apnea, bradycardia, cyanosis, vasospasm, thrombosis) was observed in 22 of 328 (6.7%) patients in whom BETs were performed (no data available in 3 BETs). Of the 22 adverse events, 6 were mild episodes of bradycardia associated with calcium infusion. If those infants are excluded, as well as 2 who experienced transient arterial spasm, the incidence of "serious morbidity" associated with the procedure itself was 5.22%.

The most recent study to report BET morbidity in the era of contemporary neonatal care provides data on infants cared for from 1980 to 1995 at the Children's Hospital and University of Washington Medical Center in Seattle. Of 106 infants receiving BET, 81 were healthy and there were no deaths; however, 1 healthy infant developed severe necrotizing enterocolitis requiring surgery. Of 25 sick infants (12 required mechanical ventilation), there were 5 deaths, and 3 developed permanent sequelae, including chronic aortic obstruction from BET via the umbilical artery, intraventricular hemorrhage with subsequent developmental delay, and sudden respiratory deterioration from a pulmonary hemorrhage and subsequent global developmental delay. The author classified the deaths as "possibly" ($n=3$) or "probably" ($n=2$) and the complications as "possibly" ($n=2$) or "probably" ($n=1$) resulting from the BET. Thus in 25 sick infants, the overall risk of death or permanent sequelae ranged from 3 of 25 to 8 of 25 (12%–32%) and of permanent sequelae in survivors from 1 of 20 to 2 of 20 (5%–10%).

Most of the mortality and morbidity rates reported date from a time at which BET was a common procedure in nurseries. This is no longer the case, and newer phototherapy techniques are likely to reduce the need for BETs even further. Because the frequency of performance of any procedure is an important determinant of risk, the fact that BET is so rarely performed today could result in higher mortality and morbidity rates. However, none of the reports before 1986 included contemporary monitoring capabilities such as pulse oximetry, which should provide earlier identification of potential problems and might decrease morbidity and mortality. In addition, current standards for the monitoring of transfused blood products has significantly reduced the risk of transfusion-transmitted viral infections.

TECHNICAL REPORT

Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

abstract

FREE

OBJECTIVE: To standardize the use of phototherapy consistent with the American Academy of Pediatrics clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

METHODS: Relevant literature was reviewed. Phototherapy devices currently marketed in the United States that incorporate fluorescent, halogen, fiber-optic, or blue light-emitting diode light sources were assessed in the laboratory.

RESULTS: The efficacy of phototherapy units varies widely because of differences in light source and configuration. The following characteristics of a device contribute to its effectiveness: (1) emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum ($\sim 460\text{--}490\text{ nm}$); (2) irradiance of at least $30\text{ }\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (confirmed with an appropriate irradiance meter calibrated over the appropriate wavelength range); (3) illumination of maximal body surface; and (4) demonstration of a decrease in total bilirubin concentrations during the first 4 to 6 hours of exposure.

RECOMMENDATIONS (SEE APPENDIX FOR GRADING DEFINITION): The intensity and spectral output of phototherapy devices is useful in predicting potential effectiveness in treating hyperbilirubinemia (group B recommendation). Clinical effectiveness should be evaluated before and monitored during use (group B recommendation). Blocking the light source or reducing exposed body surface should be avoided (group B recommendation). Standardization of irradiance meters, improvements in device design, and lower-upper limits of light intensity for phototherapy units merit further study. Comparing the in vivo performance of devices is not practical, in general, and alternative procedures need to be explored. *Pediatrics* 2011;128:e1046–e1052

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KEY WORDS

phototherapy, newborn jaundice, hyperbilirubinemia, light treatment

ABBREVIATION

LED—light-emitting diode

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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INTRODUCTION

Clinical trials have validated the efficacy of phototherapy in reducing excessive unconjugated hyperbilirubinemia, and its implementation has drastically curtailed the use of exchange transfusions.¹ The initiation and duration of phototherapy is defined by a specific range of total bilirubin values based on an infant's postnatal age and the potential risk for bilirubin neurotoxicity.¹ Clinical response to phototherapy depends on the efficacy of the phototherapy device as well as the balance between an infant's rates of bilirubin production and elimination. The active agent in phototherapy is light delivered in measurable doses, which makes phototherapy conceptually similar to pharmacotherapy. This report standardizes the use of phototherapy consistent with the American Academy of Pediatrics clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

I. COMMERCIAL LIGHT SOURCES

A wide selection of commercial phototherapy devices is available in the United States. A complete discussion of devices is beyond the scope of this review; some are described in Tables 1 and 2. Phototherapy devices can be categorized according to their light source as follows: (1) fluorescent-tube devices that emit different colors (cool white daylight, blue [B], special blue [BB], turquoise, and green) and are straight (F20 T12, 60 cm, 20 W), U-shaped, or spiral-shaped; (2) metal halide bulbs, used in spotlights and incubator lights; (3) light-emitting diodes (LEDs) or metal halide bulbs, used with fiber-optic light guides in pads, blankets, or spotlights; and (4) high-intensity LEDs, used as over- and under-the-body devices.

TABLE 1 Phototherapy Devices Commonly Used in the United States and Their Performance Characteristics

Device	Manufacturer	Distance to Patient (cm)	Footprint Area (Length × Width, cm ²)	% Treatable BSA	Spectrum, Total (nm)	Bandwidth* (nm)	Peak (nm)	Footprint Irradiance (μW/cm ² /nm)		
								Min	Max	Mean ± SD
Light Emitting Diodes [LED]	neoBLUE	30	1152 (48 × 24)	100	420–540	20	462	12	37	30 ± 7
	PortaBed	≥5	1740 (30 × 58)	100	425–540	27	463	40	76	67 ± 8
Fluorescent	BiliLite CW/BB	45	2928 (48 × 61)	100	380–720	69	578	6	10	8 ± 1
	BiliLite BB	45	2928 (48 × 61)	100	400–550	35	445	11	22	17 ± 2
	BiliLite TL52	45	2928 (48 × 61)	100	400–626	69	437	13	23	19 ± 3
	BiliBed	0	693 (21 × 33)	71	400–560	80	450	14	59	36 ± 2
Halogen	MinBiliLite	45	490 (25 diam)	54	350–800	190	580	<1	19	7 ± 5
	Phototherapy Lite	45	490 (25 diam)	54	370–850	200	590	<1	17	5 ± 5
Halogen fiber-optic	BiliBlanket	0	150 (10 × 15)	24	390–600	70	533	9	31	20 ± 6
	Wallaby II Preterm	0	117 (9 × 13)	19	400–560	45	513	8	30	16 ± 6
	Wallaby II Term	0	280 (8 × 35)	53	400–560	45	513	6	11	8 ± 1
	Spotlight 1000	45	490 (25 diam)	54	400–560	45	513	1	11	6 ± 3
	PEP Model 2000	23	1530 (30 × 51)	100	400–717	63	445	12	49	28 ± 11
	Bili Soft	0	825 (25 × 33)	71	400–670	40	453	1	52	25 ± 16

Data in Table 1 are expanded and updated from that previously reported by Vreman et al.³ The definitions and standards for device assessment are explained below.

EMISSION SPECTRAL QUALITIES: Measured data of the light delivered by each of the light sources are presented as the minimum, maximum and range. Light source emission spectra within the range of 300–700 nm were recorded after the device had reached stable light emission, using a miniature fiberoptic radiometer (IRRAD2000, Ocean Optics, Inc, Dunedin, FL). For precision based device assessment, the spectral bandwidth (*), which is defined as the width of the emission spectrum in nm at 50% of peak light intensity, is the preferred method to distinguish and compare instead of the total range emission spectrum (data usually provided by manufacturers). Emission peak values are also used to characterize the quality of light emitted by a given light source.

IRRADIANCE: Measured data are presented as mean ± standard deviation (SD), representing the irradiance of blue light (including spectral bandwidth), for each device's light footprint at the manufacturer-recommended distance. To compare diverse devices, the spectral irradiance (μW/cm²/nm) measurements were made using calibrated BiliBlanket Meters I and II (Ohmeda, GE Healthcare, Fairfield, CT), which were found to yield identical results with stable output phototherapy devices. This type of meter was selected from the several devices with different photonic characteristics that are commercially available, because it has a wide sensitivity range (400–520 nm with peak sensitivity at 450 nm), which overlaps the bilirubin absorption spectrum and which renders it suitable for the evaluation of narrow and broad wavelength band light sources. The devices have been found exceptionally stable during several years of use and agree closely after each annual calibration.

FOOTPRINT: The minimum and maximum irradiance measured (at the intervals provided or defined) in the given irradiance footprint of the device (length × width). The footprint of a device is that area which is occupied by a patient to receive phototherapy. The irradiance footprint has greater dimensions than the emission surface, which is measured at the point where the light exits a phototherapy device. The minimum and maximum values are shown to indicate the range of irradiances encountered with a device and can be used as an indication of the uniformity of the emitted light. Most devices conform to an international standard to deliver a minimum/maximum footprint light ratio of no lower than 0.4.

BSA: BODY SURFACE AREA refers to percent (%) exposure of either the ventral or dorsal planar surface exposed to light and irradiance measurements are accurate to ±0.5.

All of the reported devices are marketed in the United States except the PortaBed, which is a non-licensed Stanford-developed research device and the Dutch Crigler-Najjar Association (used by Crigler-Najjar patients).

TABLE 2 Maximum Spectral Irradiance of Phototherapy Devices (Using Commercial Light Meters at Manufacturer Recommended Distances) Compared to Clear-Sky Sunlight

Light Meter [Range, Peak]	Footprint Irradiance, ($\mu\text{W}/\text{cm}^2/\text{nm}^3$)						
	Halogen/Fiberoptic			Fluorescent		LED	
	BiliBlanket	Wallaby (Neo)		PEP Bed	Martin/Philips BB	neoBLUE	PortaBed
		II	III				
	@ Contact	@ Contact		@ 10 cm	@ 25 cm	@ 30 cm	@ 10 cm
							Level Ground
BiliBlanket Meter II [400–520, 450 nm]	34	28	34	40	69	34	76
Bili-Meter, Model 22 [425–475, 460 nm]	29	16	32	49	100	25	86
Joey Dosimeter, JD-100 [420–550, 470 nm]	53	51	60	88	174	84	195
PMA-2123 Bilirubin Detector ^a (400–520, 460 nm)	24	24	37	35	70	38	73
GoldiLux UVA Photometer, GRP-1 ^b [315–400, 365 nm]	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04
							2489

Data in Table 2 were tested and compiled by Hendrik J. Vreman (June 2007 and reverified December 2010).

** Irradiance presented to this meter exceeded its range. Measurement was made through a stainless-steel screen that attenuated the measured irradiance to 57%, which was subsequently corrected by this factor.

^a Solar Light Company, Inc., Glenside, PA 19038.

^b Oriel Instruments, Stratford, CT 06615 and SmartMeter GRP-1 with UV-A probe. GRP-1 measures UV-A light as $\mu\text{W}/\text{cm}^2$. No artificial light source delivered significant ($<0.04 \mu\text{W}/\text{cm}^2$) UV-A radiation at the distances measured.

II. STANDARDS FOR PHOTOTHERAPY DEVICES

Methods for reporting and measuring phototherapy doses are not standardized. Comparisons of commercially available phototherapy devices that use in vitro photodegradation techniques may not accurately predict clinical efficacy.² A recent report explored an approach to standardizing and quantifying the magnitude of phototherapy delivered by various devices.³ Table 1 lists technical data for some of the devices marketed in the United States.³ Factors to consider in prescribing and implementing phototherapy are (1) emission range of the light source, (2) the light intensity (irradiance), (3) the exposed (“treatable”) body surface area illuminated, and (4) the decrease in total bilirubin concentration. A measure of the effectiveness of phototherapy to rapidly configure the bilirubin molecule to less toxic photoisomers (measured in seconds) is not yet clinically available.

A. Light Wavelength

The visible white light spectrum ranges from approximately 350 to 800 nm. Bilirubin absorbs visible light most strongly in the blue region of the spectrum (~460 nm). Absorption of

light transforms unconjugated bilirubin molecules bound to human serum albumin in solution into bilirubin photoproducts (predominantly isomers of bilirubin).^{2,4,5} Because of the photo-physical properties of skin, the most effective light in vivo is probably in the blue-to-green region (~460–490 nm).² The first prototype phototherapy device to result in a clinically significant rate of bilirubin decrease used a blue (B) fluorescent-tube light source with 420- to 480-nm emission.^{6,7} More effective narrow-band special blue bulbs (F20T12/BB [General Electric, Westinghouse, Sylvania] or TL52/20W [Phillips]) were subsequently used.^{8,9} Most recently, commercial compact fluorescent-tube light sources and devices that use LEDs of narrow spectral bandwidth have been used.^{9–14} Unless specified otherwise, plastic covers or optical filters need to be used to remove potentially harmful ultraviolet light.

Clinical Context

Devices with maximum emission within the 460- to 490-nm (blue-green) region of the visible spectrum are probably the most effective for treating hyperbilirubinemia.^{2,4} Lights with broader emission also will work, al-

though not as effectively. Special blue (BB) fluorescent lights are effective but should not be confused with white lights painted blue or covered with blue plastic sheaths, which should not be used. Devices that contain high-intensity gallium nitride LEDs with emission within the 460- to 490-nm regions are also effective and have a longer lifetime (>20 000 hours), lower heat output, low infrared emission, and no ultraviolet emission.

B. Measuring Light Irradiance

Light intensity or energy output is defined by irradiance and refers to the number of photons (spectral energy) that are delivered per unit area (cm^2) of exposed skin.¹ The dose of phototherapy is a measure of the irradiance delivered for a specific duration and adjusted to the exposed body surface area. Determination of an in vivo dose-response relationship is confounded by the optical properties of skin and the rates of bilirubin production and elimination.¹ Irradiance is measured with a radiometer ($\text{W}\cdot\text{cm}^{-2}$) or spectroradiometer ($\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$) over a given wavelength band. Table 2 compares the spectral irradiance of some of the devices in the US market, as measured with different brands of me-

ters. Often, radiometers measure wavelengths that do not penetrate skin well or that are far from optimal for phototherapy and, therefore, may be of little value for predicting the clinical efficacy of phototherapy units. A direct relationship between irradiance and the rate of in vivo total bilirubin concentration decrease was described in the report of a study of term “healthy” infants with nonhemolytic hyperbilirubinemia (peak values: 15–18 mg/dL) using fluorescent Philips daylight (TL20W/54, TL20W/52) and special blue (TLAK 40W/03) lamps.^{15,16} The American Academy of Pediatrics has recommended that the irradiance for intensive phototherapy be at least $30 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ over the waveband interval 460 to 490 nm.¹ Devices that emit lower irradiance may be supplemented with auxiliary devices. Much higher doses ($>65 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$) might have (as-yet-unidentified) adverse effects. Currently, no single method is in general use for measuring phototherapy dosages. In addition, the calibration methods, wavelength responses, and geometries of instruments are not standardized. Consequently, different radiometers may show different values for the same light source.²

Clinical Context

For routine measurements, clinicians are limited by reliance on irradiance meters supplied or recommended by the manufacturer. Visual estimations of brightness and use of ordinary photometric or colorimetric light meters are inappropriate.^{1,2} Maximal irradiance can be achieved by bringing the light source close to the infant¹; however, this should not be done with halogen or tungsten lights, because the heat generated can cause a burn. Furthermore, with some fixtures, increasing the proximity may reduce the exposed body surface area. Irradiance distribution in the illuminated area

(footprint) is rarely uniform; measurements at the center of the footprint may greatly exceed those at the periphery and are variable among phototherapy devices.¹ Thus, irradiance should be measured at several sites on the infant’s body surface. The ideal distance and orientation of the light source should be maintained according to the manufacturer’s recommendations. The irradiance of all lamps decreases with use; manufacturers may provide useful-lifetime estimates, which should not be exceeded.

C. Optimal Body Surface Area

An infant’s total body surface area¹⁷ can be influenced by the disproportionate head size, especially in the more preterm infant. Complete (100%) exposure of the total body surface to light is impractical and limited by use of eye masks and diapers. Circumferential illumination (total body surface exposure from multiple directions) achieves exposure of approximately 80% of the total body surface. In clinical practice, exposure is usually planar: ventral with overhead light sources and dorsal with lighted mattresses. Approximately 35% of the total body surface (ventral or dorsal) is exposed with either method. Changing the infant’s posture every 2 to 3 hours may maximize the area exposed to light. Exposed body surface area treated rather than the number of devices (double, triple, etc) used is clinically more important. Maximal skin surface illumination allows for a more intensive exposure and may require combined use of more than 1 phototherapy device.¹

Clinical Context

Physical obstruction of light by equipment, such as radiant warmers, head covers, large diapers, eye masks that enclose large areas of the scalp, tape, electrode patches, and insulating plastic covers, decrease the exposed skin

surface area. Circumferential phototherapy maximizes the exposed area. Combining several devices, such as fluorescent tubes with fiber-optic pads or LED mattresses placed below the infant or bassinet, will increase the surface area exposed. If the infant is in an incubator, the light rays should be perpendicular to the surface of the incubator to minimize reflectance and loss of efficacy.^{1,2}

D. Rate of Response Measured by Decrease in Serum Bilirubin Concentration

The clinical impact of phototherapy should be evident within 4 to 6 hours of initiation with an anticipated decrease of more than 2 mg/dL (34 $\mu\text{mol/L}$) in serum bilirubin concentration.¹ The clinical response depends on the rates of bilirubin production, enterohepatic circulation, and bilirubin elimination; the degree of tissue bilirubin deposition^{15,16,18}; and the rates of the photochemical reactions of bilirubin. Aggressive implementation of phototherapy for excessive hyperbilirubinemia, sometimes referred to as the “crash-cart” approach,^{19,20} has been reported to reduce the need for exchange transfusion and possibly reduce the severity of bilirubin neurotoxicity.

Clinical Context

Serial measurements of bilirubin concentration are used to monitor the effectiveness of phototherapy, but the value of these measurements can be confounded by changes in bilirubin production or elimination and by a sudden increase in bilirubin concentration (rebound) if phototherapy is stopped. Periodicity of serial measurements is based on clinical judgment.

III. EVIDENCE FOR EFFECTIVE PHOTOTHERAPY

Light-emission characteristics of phototherapy devices help in predicting

TABLE 3 Practice Considerations for Optimal Administration of Phototherapy

Checklist	Recommendation	Implementation
Light source (nm)	Wavelength spectrum in ~460- 490-nm blue-green light region	Know the spectral output of the light source
Light irradiance ($\mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$)	Use optimal irradiance: $>30 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ within the 460- to 490-nm waveband	Ensure uniformity over the light footprint area
Body surface area (cm^2)	Expose maximal skin area	Reduce blocking of light
Timeliness of implementation	Urgent or “crash-cart” intervention for excessive hyperbilirubinemia	May conduct procedures while infant is on phototherapy
Continuity of therapy	Briefly interrupt for feeding, parental bonding, nursing care	After confirmation of adequate bilirubin concentration decrease
Efficacy of intervention	Periodically measure rate of response in bilirubin load reduction	Degree of total serum/plasma bilirubin concentration decrease
Duration of therapy	Discontinue at desired bilirubin threshold; be aware of possible rebound increase	Serial bilirubin measurements based on rate of decrease

their effectiveness (group B recommendation) (see Appendix). The clinical effectiveness of the device should be known before and monitored during clinical application (group B recommendation). Local guidelines (instructions) for routine clinical use should be available. Important factors that need to be considered are listed in Table 3. Obstructing the light source and reducing the exposed body surface area must be avoided (group B recommendation).

These recommendations are appropriate for clinical care in high-resource settings. In low-resource settings the use of improvised technologies and affordable phototherapy device choices need to meet minimum efficacy and safety standards.

IV. SAFETY AND PROTECTIVE MEASURES

A clinician skilled in newborn care should assess the neonate's clinical status during phototherapy to ensure adequate hydration, nutrition, and temperature control. Clinical improvement or progression of jaundice should also be assessed, including signs suggestive of early bilirubin encephalopathy such as changes in sleeping pattern, deteriorating feeding pattern, or inability to be consoled while crying.¹ Staff should be educated

regarding the importance of safely minimizing the distance of the phototherapy device from the infant. They should be aware that the intensity of light decreases at the outer perimeter of the light footprint and recognize the effects of physical factors that could impede or obstruct light exposure. Staff should be aware that phototherapy does not use ultraviolet light and that exposure to the lights is mostly harmless. Four decades of neonatal phototherapy use has revealed no serious adverse clinical effects in newborn infants 35 or more weeks of gestation. For more preterm infants, who are usually treated with prophylactic rather than therapeutic phototherapy, this may not be true. Informed staff should educate parents regarding the care of their newborn infant undergoing phototherapy. Devices must comply with general safety standards listed by the International Electrotechnical Commission.²¹ Other clinical considerations include:

a. Interruption of phototherapy: After a documented decrease in bilirubin concentration, continuous exposure to the light source may be interrupted and the eye mask removed to allow for feeding and maternal-infant bonding.¹

- b. Use of eye masks: Eye masks to prevent retinal damage are used routinely, although there is no evidence to support this recommendation. Retinal damage has been documented in the unpatched eyes of newborn monkeys exposed to phototherapy, but there are no similar data available from human newborns, because eye patches have always been used.^{22–24} Purulent eye discharge and conjunctivitis in term infants have been reported with prolonged use of eye patches.^{25,26}
- c. Use of diapers: Concerns for the long-term effects of continuous phototherapy exposure of the reproductive system have been raised but not substantiated.^{27–29} Diapers may be used for hygiene but are not essential.
- d. Other protective considerations: Devices used in environments with high humidity and oxygen must meet electrical and fire hazard safety standards.²¹ Phototherapy is contraindicated in infants with congenital porphyria or those treated with photosensitizing drugs.¹ Prolonged phototherapy has been associated with increased oxidant stress and lipid peroxidation³⁰ and riboflavin deficiency.³¹ Recent clinical reports of other adverse outcomes (eg, malignant melanoma, DNA damage, and skin changes) have yet to be validated.^{1,2,32,33} Phototherapy does not exacerbate hemolysis.³⁴

V. RESEARCH NEEDS

Among the gaps in knowledge that remain regarding the use of phototherapy to prevent severe neonatal hyperbilirubinemia, the following are among the most important:

1. The ability to measure the actual wavelength and irradiance delivered by a phototherapy device is urgently needed to assess the efficiency of

phototherapy in reducing total serum bilirubin concentrations.

2. The safety and efficacy of home phototherapy remains a research priority.
3. Further delineation of the short- and long-term consequences of exposing infants with conjugated and unconjugated hyperbilirubinemia to phototherapy is needed.
4. Whether use of phototherapy reduces the risk of bilirubin neurotoxicity in a timely and effective manner needs further exploration.

SUMMARY

Clinicians and hospitals should ensure that the phototherapy devices they use fully illuminate the patient's body sur-

face area, have an irradiance level of $\geq 30 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (confirmed with accuracy with an appropriate spectral radiometer) over the waveband of approximately 460 to 490 nm, and are implemented in a timely manner. Standard procedures should be documented for their safe deployment.

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APPENDIX Definition of Grades for Recommendation and Suggestion for Practice

Grade	Definition	Suggestion for Practice
A	This intervention is recommended. There is a high certainty that the net benefit is substantial	Offer and administer this intervention
B	This intervention is recommended. There is a moderate certainty that the net benefit is moderate to substantial	Offer and administer this intervention
C	This intervention is recommended. There may be considerations that support the use of this intervention in an individual patient. There is a moderate to high certainty that the net benefit is small	Offer and administer this intervention only if other considerations support this intervention in an individual patient
D	This intervention is not recommended. There is a moderate to high certainty that the intervention has no net benefit and that the harms outweigh the benefits	Discourage use of this intervention
I	The current evidence is insufficient to assess the balance of benefits against and harms of this intervention. There is a moderate to high certainty that the intervention has no net benefit and that the harms outweigh the benefits. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined	If this intervention is conducted, the patient should understand the uncertainty about the balance of benefits and harms

US Preventive Services Task Force Grade definitions, May, 2008 (available at www.uspreventiveservicestaskforce.org/3rduspstf/ratings.htm).

Hyperbilirubinemia in the Newborn Infant ≥ 35 Weeks' Gestation: An Update With Clarifications

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ABBREVIATIONS

AAP—American Academy of Pediatrics
G6PD—glucose-6-phosphate dehydrogenase
TSB—total serum bilirubin
TcB—transcutaneous bilirubin

Opinions expressed in this commentary are those of the author and not necessarily those of the American Academy of Pediatrics or its Committees.

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In July 2004, the Subcommittee on Hyperbilirubinemia of the American Academy of Pediatrics (AAP) published its clinical practice guideline on the management of hyperbilirubinemia in the newborn infant ≥ 35 weeks of gestation,¹ and a similar guideline was published in 2007 by the Canadian Paediatric Society.² Experience with implementation of the AAP guideline suggests that some areas require clarification. The 2004 AAP guideline also expressed hope that its implementation would “reduce the incidence of severe hyperbilirubinemia and bilirubin encephalopathy. . . .” We do not know how many practitioners are following the guideline, nor do we know the current incidence of bilirubin encephalopathy in the United States. We do know, however, that kernicterus is still occurring in the United States, Canada, and Western Europe.^{3–7} In 2002, the National Quality Forum suggested that kernicterus should be classified as a “serious reportable event,”⁸ sometimes termed a “never event,”⁹ implying that with appropriate monitoring, surveillance, and intervention, this devastating condition can, or should, be eliminated. Although this is certainly a desirable objective, it is highly unlikely that it can be achieved given our current state of knowledge and practice.¹⁰ In certain circumstances (notably, glucose-6-phosphate dehydrogenase [G6PD] deficiency, sepsis, genetic predisposition, or other unknown stressors), acute, severe hyperbilirubinemia can occur and can produce brain damage despite appropriate monitoring and intervention.

In addition to clarifying certain items in the 2004 AAP guideline, we recommend universal predischarge bilirubin screening using total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) measurements, which help to assess the risk of subsequent severe hyperbilirubinemia. We also recommend a more structured approach to management and follow-up according to the predischarge TSB/TcB, gestational age, and other risk factors for hyperbilirubinemia. These recommendations represent a consensus of expert opinion based on the available evidence, and they are supported by several independent reviewers. Nevertheless, their efficacy in preventing kernicterus and their cost-effectiveness are unknown.

METHODS

We reviewed the report on screening for neonatal hyperbilirubinemia published by the Agency for Healthcare Research and Quality and prepared by the Tufts-New England Medical Center Evidence-Based Practice Center,¹¹ the current report by the US Preventive Services Task Force,¹² and other relevant literature.^{1,3–10,13–26}

TABLE 1 Important Risk Factors for Severe Hyperbilirubinemia

Predischarge TSB or TcB measurement in the high-risk or high-intermediate-risk zone
Lower gestational age
Exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive
Jaundice observed in the first 24 h
Isoimmune or other hemolytic disease (eg, G6PD deficiency)
Previous sibling with jaundice
Cephalohematoma or significant bruising
East Asian race

RISK FACTORS

The 2004 AAP guideline includes 2 categories of risk factors, but the distinction between these 2 categories has not been clear to all users of the guideline.

Laboratory and Clinical Factors That Help to Assess the Risk of Subsequent Severe Hyperbilirubinemia

These “risk factors for hyperbilirubinemia” are listed in Table 1. Understanding the predisposition to subsequent hyperbilirubinemia provides

guidance for timely follow-up as well as the need for additional clinical and laboratory evaluation.

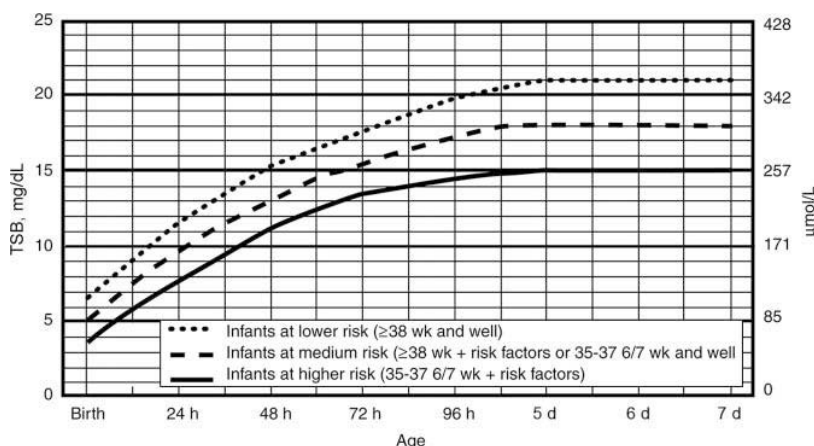
Laboratory and Clinical Factors That Might Increase the Risk of Brain Damage in an Infant Who Has Hyperbilirubinemia

These risk factors for bilirubin neurotoxicity are listed in the figures of the 2004 AAP guideline that provide recommendations for the use of phototherapy and exchange transfusion. These “neurotoxicity risk factors” encompass those that might increase the risk

TABLE 2 Hyperbilirubinemia Neurotoxicity Risk Factors

Isoimmune hemolytic disease
G6PD deficiency
Asphyxia
Sepsis
Acidosis
Albumin <3.0 mg/dL

of brain damage in an infant who has severe hyperbilirubinemia¹ (see Fig 1 and Table 2). The neurotoxicity risk factors are used in making the decision to initiate phototherapy or perform an exchange transfusion. These interventions are recommended at a lower bilirubin level when any of the neurotoxicity risk factors is present. Some conditions are found in both risk-factor categories. For example, lower gestational age and isoimmune hemolytic disease increase the likelihood of subsequent severe hyperbilirubinemia as well as the risk of brain damage by bilirubin.

**FIGURE 1**

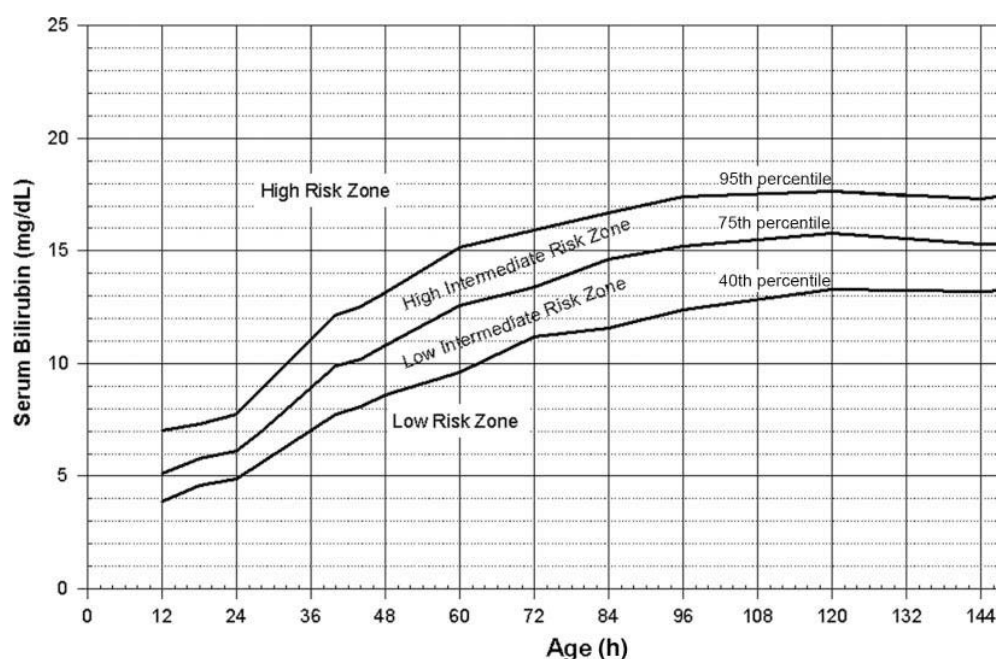
Guidelines for phototherapy in hospitalized infants ≥35 weeks' gestation. Note that these guidelines are based on limited evidence and that the levels shown are approximations. The guidelines refer to the use of intensive phototherapy, which should be used when the TSB level exceeds the line indicated for each category.

- Use total bilirubin. Do not subtract direct-reacting or conjugated bilirubin.
- Risk factors are isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis, or an albumin level of <3.0 g/dL (if measured).
- For well infants at 35 to 37½ weeks' gestation, one can adjust TSB levels for intervention around the medium-risk line. It is an option to intervene at lower TSB levels for infants closer to 35 weeks' gestation and at higher TSB levels for those closer to 37½ weeks' gestation.
- It is an option to provide conventional phototherapy in the hospital or at home at TSB levels of 2 to 3 mg/dL (35–50 μmol/L) below those shown, but home phototherapy should not be used in any infant with risk factors.

PREDISCHARGE RISK ASSESSMENT FOR SUBSEQUENT SEVERE HYPERBILIRUBINEMIA

The 2004 AAP guideline recommends a predischarge bilirubin measurement and/or assessment of clinical risk factors to evaluate the risk of subsequent severe hyperbilirubinemia.¹ New evidence suggests that combining a predischarge measurement of TSB or TcB with clinical risk factors might improve the prediction of the risk of subsequent hyperbilirubinemia.^{13,14,23} In addition, when interpreted by using the hour-specific nomogram (Fig 2), measurement of TSB or TcB also provides a quantitative assessment of the degree of hyperbilirubinemia. This provides guidance regarding the need (or lack of need) for additional testing to identify a cause of the hyperbilirubinemia and for additional TSB measurements.¹

The TSB can be measured from the same sample that is drawn for the

**FIGURE 2**

Nomogram for designation of risk in 2840 well newborns at ≥ 36 weeks' gestational age with birth weight of ≥ 2000 g or ≥ 35 weeks' gestational age and birth weight of ≥ 2500 g based on the hour-specific serum bilirubin values. (Reproduced with permission from Bhutani VK, Johnson L, Sivieri EM. *Pediatrics*. 1999;103[1]:6–14.)

metabolic screen. The risk zone (Fig 2) and the other clinical risk factors (Table 3) are then combined to assess the risk of subsequent hyperbilirubinemia and to formulate a plan for management and follow-up (Fig 3). When combined with the risk zone, the factors that are most predictive of hyperbilirubinemia risk are lower gestational age and exclusive breastfeeding.^{13,14,23} The lower the gestational age, the greater the risk of developing hyperbilirubinemia.^{13,14,23} For those infants from whom ≥ 2 successive TSB or TcB measurements are obtained, it is helpful to plot the data on the nomogram¹⁵ to assess the rate of rise. Hemolysis is likely if the TSB/TcB is crossing percentiles on the nomogram and suggests the need for further testing and follow-up (see Table 1 in the 2004 AAP guideline). Therefore, we recommend that a pre-discharge measurement of TSB or TcB be performed and the risk zone for hyperbilirubinemia determined¹⁵ on the

basis of the infant's age in hours and the TSB or TcB measurement.

It should be noted that, even with a low pre-discharge TSB or TcB level, the risk of subsequent hyperbilirubinemia is not zero,^{13,17} so appropriate follow-up should always be provided (Fig 3).

RESPONSE TO PREDISCHARGE TSB MEASUREMENTS

Figure 3 provides our recommendations for management and follow-up, according to pre-discharge screening. Note that this algorithm represents a consensus of the authors and is based on interpretation of limited evidence (see below).

FOLLOW-UP AFTER DISCHARGE

Most infants discharged at < 72 hours should be seen within 2 days of discharge.

Earlier follow-up might be necessary for infants who have risk factors for severe hyperbilirubinemia,^{1,13,14,23} whereas those in the lower risk zones with few or no risk factors can be seen later (Fig 3). Figure 3 also provides additional suggestions for evaluation and management at the first follow-up visit.

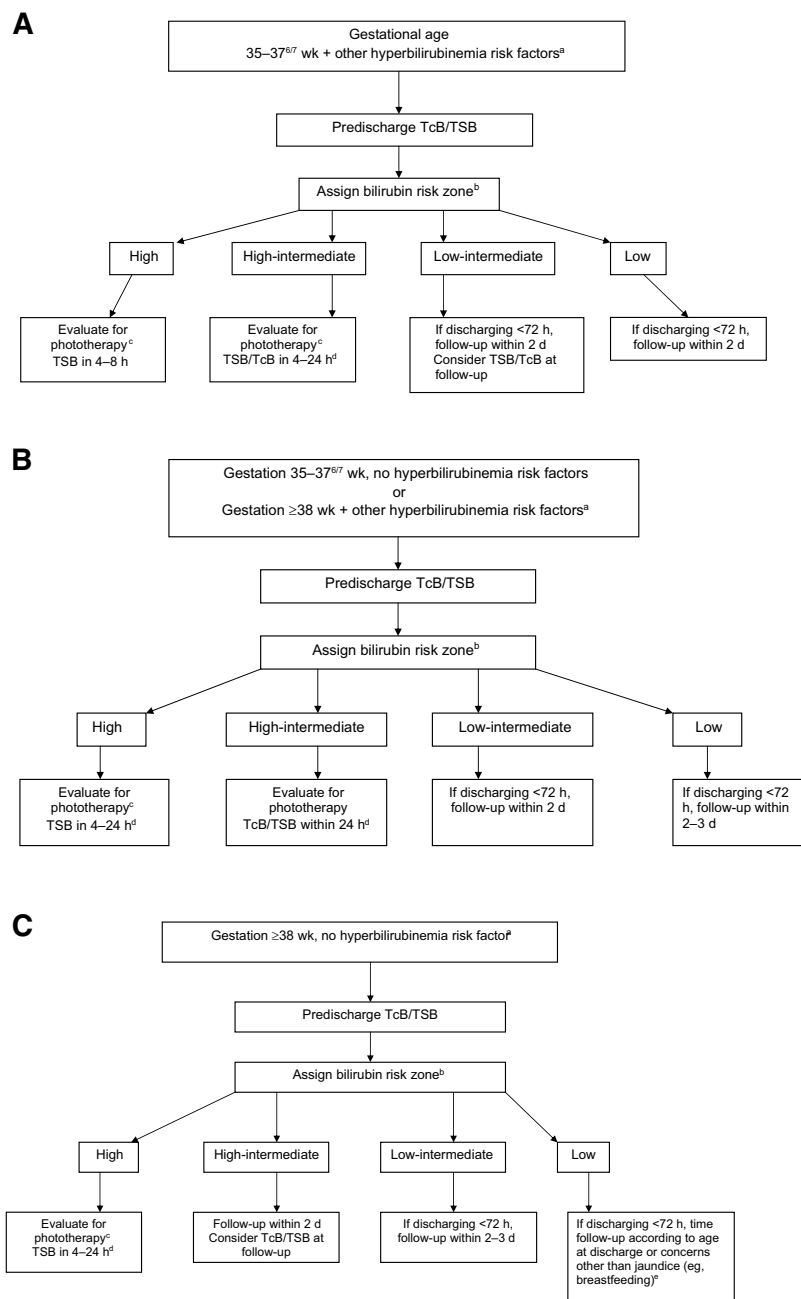
TcB MEASUREMENTS

TcB measurements are being used with increasing frequency in hospi-

TABLE 3 Other Risk Factors for Severe Hyperbilirubinemia to be Considered with the Gestational Age and the Pre-discharge TSB or TcB level (see Figure 3)

Exclusive breastfeeding, particularly if nursing is not going well and/or weight loss is excessive ($> 8 - 10\%$)
Isoimmune or other hemolytic disease (eg, G6PD deficiency, hereditary spherocytosis)
Previous sibling with jaundice
Cephalohematoma or significant bruising
East Asian race

The gestational age and the pre-discharge TSB or TcB level are the most important factors that help to predict the risk of hyperbilirubinemia. The risk increases with each decreasing week of gestation from 42–35 weeks (see Figure 3)

**FIGURE 3**

Algorithm providing recommendations for management and follow-up according to predischarge bilirubin measurements, gestation, and risk factors for subsequent hyperbilirubinemia.

- Provide lactation evaluation and support for all breastfeeding mothers.
- Recommendation for timing of repeat TSB measurement depends on age at measurement and how far the TSB level is above the 95th percentile (Fig 2). Higher and earlier initial TSB levels require an earlier repeat TSB measurement.
- Perform standard clinical evaluation at all follow-up visits.
- For evaluation of jaundice see 2004 AAP guideline.¹
- ^a Table 3. ^b Fig 2. ^c Fig 1. ^d In hospital or as outpatient. ^e Follow-up recommendations can be modified according to level of risk for hyperbilirubinemia; depending on the circumstances in infants at low risk, later follow-up can be considered.

tal nurseries and in some outpatient settings. They have the advantage of providing instantaneous information and probably reduce the likelihood of missing a clinically significant TSB, making them particularly useful in outpatient practice. TcB measurements can significantly reduce the number of TSB measurements that are required, but as with any point-of-care test, regular monitoring for appropriate quality assurance by comparison with TSB measurements is necessary. Significant variation can occur among instruments, and the use of a new instrument should be compared with hospital laboratory measurements to ensure that the instrument is working properly; such checks should be performed periodically. TcB is a measurement of the yellow color of the blanched skin and subcutaneous tissue, not the serum, and should be used as a screening tool to help determine whether the TSB should be measured. Although TcB measurements provide a good estimate of the TSB level, they are not a substitute for TSB values, and a TSB level should always be obtained when therapeutic intervention is being considered.

Most studies in term and late-preterm infants have indicated that the TcB tends to underestimate the TSB, particularly at higher TSB levels.¹⁸ Thus, investigators have adopted various techniques to avoid missing a high TSB level (ie, a false-negative TcB measurement). These techniques include measuring the TSB if

- the TcB value is at 70% of the TSB level recommended for the use of phototherapy¹⁹;
- the TcB value is above the 75th percentile on the Bhutani nomogram (Fig 1)¹⁵ or the 95th percentile on a TcB nomogram¹⁶ (in 1 study, if the TcB was <75th percentile on the Bhutani nomogram, 0 of 349 infants

had a TSB level above the 95th percentile [a negative predictive value of 100%]²⁰; or

- at follow-up after discharge, the TcB value is >13 mg/dL ($222 \mu\text{mol/L}$)²¹ (in this outpatient study, no infant who had a TcB value of ≤ 13 mg/dL had a TSB level of >17 mg/dL [$291 \mu\text{mol/L}$]).²¹

COSTS

The introduction of universal predischarge bilirubin screening, follow-up visits, and TSB/TcB measurements might increase costs. Ideally, a cost/benefit analysis should include the cost to prevent 1 case of kernicterus. The cost per case, however, highly depends on the incidence of kernicterus as well as its potential reduction resulting from the intervention. By using a strategy similar to that suggested in this guideline, and assuming an incidence of kernicterus of 1 in 100 000 live births and a relative risk reduction of 70%, the cost to prevent 1 case of kernicterus has been estimated as approximately \$5.7 million.²² Because we do not know the current incidence of kernicterus in the United States or the actual relative risk reduction (if these guidelines were implemented universally), we cannot calculate the true cost/benefit ratio. Taking into account the lifetime cost of an infant with kernicterus, it is possible that there could be savings.²²

DISCUSSION

While endeavoring to clarify some areas addressed in the 2004 AAP guideline, we have also introduced new recommendations, both for the predis-

charge assessment of the risk of subsequent hyperbilirubinemia and for follow-up testing. We recognize that the quality of evidence for recommending universal predischarge screening and for the suggested management and follow-up (Fig 3) is limited and, in the absence of higher levels of evidence, our recommendations must, therefore, be based on expert opinion. As indicated in the reviews by the US Preventive Services Task Force¹² and Trikalinos et al¹¹ in this issue of *Pediatrics*, there are currently no good data to indicate that the implementation of these recommendations will reduce the risk of kernicterus, although published data suggest that predischarge screening can reduce the incidence of a TSB level of ≥ 25 mg/dL,^{24,25} perhaps by increasing the use of phototherapy.²⁴ Nevertheless, because kernicterus is a devastating condition that leads to serious and permanent neurologic damage, and because published reports and our own review of cases in the medicolegal setting suggest that many of these cases could have been prevented, a reasonable argument can be made for implementing the suggested recommendations in the absence of better evidence. Because kernicterus is a rare condition, it is unlikely that we will be able to obtain adequate evidence in the short-term to support our recommendations. In their elegant polemic, Auerbach et al²⁶ discussed "the tension between needing to improve care and knowing how to do it." They noted that, in the absence of appropriate evidence, "bold efforts at improvement can consume tremendous resources yet confer only a small benefit."²⁶ We

also recognize that although predischarge testing is relatively inexpensive and convenient, measuring the TSB after discharge is more difficult. TcB measurement is quite easy but is not currently available in most primary care settings. In addition, more evidence is needed to support the cost and efficacy of these recommendations. There is certainly a risk that these recommendations could lead to additional testing and an increase in both appropriate and inappropriate use of phototherapy.^{1,24} Nevertheless, it is our opinion that universal screening, when combined with the clinical risk factors (of which gestational age and exclusive breastfeeding are most important) and targeted follow-up, is a systems approach that is easy to implement and understand, and it provides a method of identifying infants who are at high or low risk for the development of severe hyperbilirubinemia. In addition to risk assessment, the measurement of TSB or TcB when interpreted by using the hour-specific nomogram provides the caregiver with an immediate and quantitative mechanism for assessing the degree of hyperbilirubinemia and the need for additional surveillance and testing. As such, it could play an important role in preventing acute bilirubin encephalopathy, although this has yet to be demonstrated.

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Universal Bilirubin Screening, Guidelines, and Evidence

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ABBREVIATIONS

AAP—American Academy of Pediatrics
USPSTF—US Preventive Services Task Force
TSB—total serum bilirubin

Opinions expressed in these commentaries are those of the author and not necessarily those of the American Academy of Pediatrics or its Committees.

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In a commentary¹ and update of the 2004 American Academy of Pediatrics (AAP) guideline "Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation"² in this issue of *Pediatrics*, Maisels et al recommend that all newborns have a bilirubin measurement before discharge from their birth hospitalization. In contrast, a recommendation statement from the US Preventive Services Task Force (USPSTF),³ supported by a systematic review,⁴ concludes that evidence is insufficient to make that recommendation. As an author of the commentary¹ and the 2004 AAP jaundice guideline² who also has been critical of guidelines based on insufficient evidence,^{5–11} I have felt particularly torn about this recommendation.

Perhaps partly because I have served as an expert consultant on dozens of heartbreaking kernicterus legal cases,¹² I find the argument in favor of universal bilirubin screening and systematic follow-up persuasive. We know kernicterus is devastating and that, although rare, cases are continuing to occur. Furthermore, anecdotal evidence suggests that many cases could have been prevented by earlier measurement of bilirubin levels, leading to closer follow-up and earlier initiation of appropriate therapy.^{13,14} We have not had randomized trials to show that universal screening and systematic follow-up will lead to a reduction in kernicterus, but considerable research in the area of optimizing patient safety suggests that there is room for improvement in the 2004 guidelines. Specifically, we know that in the absence of universal screening, detection and management of clinically significant hyperbilirubinemia during the birth hospitalization relies on several imperfect steps: (1) nurses and doctors need to remember to examine the infant for jaundice; (2) they need to distinguish visually between jaundice that is and is not clinically significant for the infant's age in hours; and (3) they need to combine information from this visual assessment of jaundice and/or a total serum bilirubin (TSB) level with knowledge of the newborn's other risk factors to determine the need for and timing of bilirubin measurements, follow-up visits, and treatments. We also know that nurseries are busy places and that sometimes people may not do things that they should¹⁵ or might do them under suboptimal conditions, such as assessing jaundice in the dim light found in many hospital rooms. Finally, compared with the devastating effects of kernicterus, the costs and risks of screening seem low, particularly with a transcutaneous bilirubinometer, which may actually decrease the number of serum bilirubin measurements obtained.¹⁶

On the other hand, as a proponent of evidence-based medicine, I recognize the insufficiency of the data to support the recommendation.^{3,4} The rationale outlined above would apply whether the incidence of kernicterus were 1 in 10 000 or 1 in 1 million, but surely the potential benefits of screening depend on how much kernicterus there is to

prevent, and this is not known. Even if we knew the incidence of kernicterus, the proportion that might be preventable by screening and systematic follow-up is unclear. Although plaintiffs in malpractice cases commonly assert that infants with bilirubin levels in the 40s at 4 or 5 days must have had proportionately high levels at the time of discharge (even if no or minimal jaundice was noted at that time), there is little evidence to support this assertion. Studies of the predictive value of early bilirubin levels have had much lower levels of hyperbilirubinemia (TSB of 17–20 mg/dL).³ Because they may have different causes, such as glucose-6-phosphate dehydrogenase deficiency and infection, the very high levels that lead to kernicterus may be less predictable. Moreover, several studies have revealed that in the absence of any jaundice, a TSB level of ≥ 12 mg/dL is extremely unlikely.^{17–20} As an experienced generalist who believes he can recognize at least some newborns who definitely are not jaundiced, I sympathize with colleagues who may question the cost-efficacy of measuring bilirubin (particularly if it involves an additional poke or trying to squeeze more blood out of a recalcitrant heel) in a light-skinned 2-day-old who has no hint of jaundice. Requiring a bilirubin measurement for every such infant because some clinicians may forget or be careless feels like keeping the whole class after school for the transgressions of a few.

After doing my best to reconcile these opposing viewpoints, I believe that universal pre-discharge bilirubin screening is a good idea but that the evidence is not sufficient to recommend it in an AAP guideline. This is consistent with AAP policy. In a 2004 statement, the Steering Committee on Quality Improvement and Management outlined levels of evidence and strengths of AAP guidelines.²¹ The policy stated that ex-

cept in “exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm,” if the level of evidence is “expert opinion, case reports, and reasoning from first principles,” a course of action should be designated an option rather than a recommendation. Because, as is explicitly acknowledged in the commentary, expert opinion, case reports, and reasoning from first principles are exactly the level of evidence that supports the recommendation for universal bilirubin screening, and because we wanted to make that recommendation, it needed to be published as a commentary rather than a guideline.

Is this AAP policy on evidence and guideline recommendations a good one? I believe it is. Practicing clinicians need and appreciate guidance from experts, but they also recognize the impossibility of following every guideline that an expert committee might recommend for them and need protection from well-meaning but sometimes paternalistic committees with their own agendas.²² Guideline committees tend to be dominated by academics and subspecialists with special interest, expertise, and even emotional investment in the diseases for which they are producing guidelines.²³ Most of us authors of the hyperbilirubinemia commentary are no exception.^{12,24} Although interest and expertise are invaluable, the career focus on a particular disease, with resulting close relationships with funders, patients, advocacy groups, industry, and each other, may lead to a narrow perspective in which heroic efforts at preventing or treating the target disease feel justified, even when a favorable balance of benefits over risks and costs is uncertain.²⁵ And, although slavishly adhering to evidence standards could lead to failure to recommend beneficial treatments^{25,26} even what seem

like obvious, common-sense interventions can have unintended adverse consequences.^{27,28}

The USPSTF uses a different model for producing guidelines, in which expertise at appraising and synthesizing evidence trumps disease-specific expertise.²⁹ Recommendations of the USPSTF are typically based on the results of systematic reviews of evidence, often performed by one of the Agency for Healthcare Research and Quality’s evidence-based practice centers. Such thorough reviews are not within time, expertise, and budget constraints of most guideline committees. Ironically, however, the recommendation to measure a bilirubin level for every infant before discharge was the subject of just such a review,⁴ which concluded that the evidence is insufficient to make a recommendation for or against universal bilirubin screening (“I” rating).³

The USPSTF statement comments not only on the lack of evidence that universal bilirubin screening will prevent bilirubin encephalopathy but also on the insufficiency of evidence regarding risks and efficacy of phototherapy.³ This is important, because an unintended consequence of institution of universal bilirubin screening might be a greater focus on the danger of hyperbilirubinemia, leading to excessive use of phototherapy. There is evidence that this has occurred in the Northern California Kaiser Permanente Medical Care Program, in which increased bilirubin testing was associated with a decrease in bilirubin levels of >25 mg/dL and also an increase in use of phototherapy at levels lower than those recommended in the 2004 AAP guideline.³⁰ Thus, it is worth stressing that the recommendation for bilirubin screening should not be misinterpreted as suggesting the need for phototherapy at lower bilirubin levels.

The Maisels et al commentary on hyperbilirubinemia published in this is-

sue came about because of a need to clarify the 2004 guideline and because the AAP had been asked for a statement that either recommended universal bilirubin screening or explained why not. I suspect that having the recommendation for universal screening come in the form of a commentary,

rather than a guideline, will be disappointing to both advocates and opponents of universal screening. However, I believe it is the right decision. For now, it represents what some bilirubin experts believe is reasonable on the basis of limited evidence. With additional research, we hope to be able to

make a stronger recommendation in the future.

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Hyperbilirubinemia Clinical Practice Guideline

Quick Reference Tools

- Recommendation Summary
— Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Hyperbilirubinemia
- AAP Patient Education Handout
— *Jaundice and Your Newborn*

Recommendation Summary

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

The following are the key elements of the recommendations provided by this guideline. Clinicians should:

1. Promote and support successful breastfeeding.
2. Establish nursery protocols for the identification and evaluation of hyperbilirubinemia.
3. Measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours.
4. Recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
5. Interpret all bilirubin levels according to the infant's age in hours.
6. Recognize that infants at less than 38 weeks' gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring.
7. Perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia.
8. Provide parents with written and verbal information about newborn jaundice.
9. Provide appropriate follow-up based on the time of discharge and the risk assessment.
10. Treat newborns, when indicated, with phototherapy or exchange transfusion.

Coding Quick Reference for Hyperbilirubinemia

ICD-9-CM	ICD-10-CM
774.2 Jaundice of prematurity	P59.0 Neonatal jaundice associated with preterm delivery
774.39 Jaundice, newborn, breast milk	P59.3 Neonatal jaundice from breast milk inhibitor
774.6 Jaundice, newborn, physiologic jaundice	P59.9 Neonatal jaundice, unspecified
782.4 Jaundice, unspecified, not newborn	R17 Unspecified jaundice

Jaundice and Your Newborn



Congratulations on the birth of your new baby!

To make sure your baby's first week is safe and healthy, it is important that

1. You find a pediatrician you are comfortable with for your baby's ongoing care.
2. Your baby is checked for jaundice in the hospital.
3. If you are breastfeeding, you get the help you need to make sure it is going well.
4. Make sure your baby is seen by a doctor or nurse at 3 to 5 days of age.
5. If your baby is discharged before age 72 hours, your baby should be seen by a doctor or nurse within 2 days of discharge from the hospital.

Q: What is jaundice?

A: Jaundice is the yellow color seen in the skin of many newborns. It happens when a chemical called *bilirubin* builds up in the baby's blood. Jaundice can occur in babies of any race or color.

Q: Why is jaundice common in newborns?

A: Everyone's blood contains bilirubin, which is removed by the liver. Before birth, the mother's liver does this for the baby. Most babies develop jaundice in the first few days after birth because it takes a few days for the baby's liver to get better at removing bilirubin.

Q: How can I tell if my baby is jaundiced?

A: The skin of a baby with jaundice usually appears yellow. The best way to see jaundice is in good light, such as daylight or under fluorescent lights. Jaundice usually appears first in the face and then moves to the chest, abdomen, arms, and legs as the bilirubin level increases. The whites of the eyes may also be yellow. Jaundice may be harder to see in babies with darker skin color.

Q: Can jaundice hurt my baby?

A: Most babies have mild jaundice that is harmless, but in unusual situations the bilirubin level can get very high and might cause brain damage. This is why newborns should be checked carefully for jaundice and treated to prevent a high bilirubin level.

Q: How should my baby be checked for jaundice?

A: If your baby looks jaundiced in the first few days after birth, your baby's doctor or nurse may use a skin or blood test to check your baby's bilirubin level. However, because estimating the bilirubin level based on the baby's appearance can be difficult, some experts recommend that a skin or blood test be done even if your baby does not appear jaundiced. A bilirubin level is always needed if jaundice develops before the baby is 24 hours

old. Whether a test is needed after that depends on the baby's age, the amount of jaundice, and whether the baby has other factors that make jaundice more likely or harder to see.

Q: Does breastfeeding affect jaundice?

A: Jaundice is more common in babies who are breastfed than babies who are formula-fed, but this occurs mainly in newborns who are not nursing well. If you are breastfeeding, you should nurse your baby at least 8 to 12 times a day for the first few days. This will help you produce enough milk and will help to keep the baby's bilirubin level down. If you are having trouble breastfeeding, ask your baby's doctor or nurse or a lactation specialist for help. Breast milk is the ideal food for your baby.

Q: When should my newborn get checked after leaving the hospital?

A: It is important for your baby to be seen by a nurse or doctor when the baby is between 3 and 5 days old, because this is usually when a baby's bilirubin level is highest. This is why, if your baby is discharged before age 72 hours, your baby should be seen within 2 days of discharge. The timing of this visit may vary depending on your baby's age when released from the hospital and other factors.

Q: Which babies require more attention for jaundice?

A: Some babies have a greater risk for high levels of bilirubin and may need to be seen sooner after discharge from the hospital. Ask your doctor about an early follow-up visit if your baby has any of the following:

- A high bilirubin level before leaving the hospital
- Early birth (more than 2 weeks before the due date)
- Jaundice in the first 24 hours after birth
- Breastfeeding that is not going well
- A lot of bruising or bleeding under the scalp related to labor and delivery
- A parent, brother, or sister who had high bilirubin and received light therapy

Q: When should I call my baby's doctor?

A: Call your baby's doctor if

- Your baby's skin turns more yellow.
- Your baby's abdomen, arms, or legs are yellow.
- The whites of your baby's eyes are yellow.
- Your baby is jaundiced and is hard to wake, fussy, or not nursing or taking formula well.

Q: How is harmful jaundice prevented?

A: Most jaundice requires no treatment. When treatment is necessary, placing your baby under special lights while he or she is undressed will lower the bilirubin level. Depending on your baby's bilirubin level, this can be done in the hospital or at home. Jaundice is treated at levels that are much lower than those at which brain damage is a concern. Treatment can prevent the harmful effects of jaundice. Putting your baby in sunlight is not recommended as a safe way of treating jaundice. Exposing your baby to sunlight might help lower the bilirubin level, but this will only work if the baby is completely undressed. This cannot be done safely inside your home because your baby will get cold, and newborns should never be put in direct sunlight outside because they might get sunburned.

Q: When does jaundice go away?

A: In breastfed babies, jaundice often lasts for more than 2 to 3 weeks. In formula-fed babies, most jaundice goes away by 2 weeks. If your baby is jaundiced for more than 3 weeks, see your baby's doctor.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor



The Diagnosis and Management of Acute Otitis Media

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- *Clinical Practice Guideline*

CLINICAL PRACTICE GUIDELINE

The Diagnosis and Management of Acute Otitis Media

abstract

FREE

This evidence-based clinical practice guideline is a revision of the 2004 acute otitis media (AOM) guideline from the American Academy of Pediatrics (AAP) and American Academy of Family Physicians. It provides recommendations to primary care clinicians for the management of children from 6 months through 12 years of age with uncomplicated AOM.

In 2009, the AAP convened a committee composed of primary care physicians and experts in the fields of pediatrics, family practice, otolaryngology, epidemiology, infectious disease, emergency medicine, and guideline methodology. The subcommittee partnered with the Agency for Healthcare Research and Quality and the Southern California Evidence-Based Practice Center to develop a comprehensive review of the new literature related to AOM since the initial evidence report of 2000. The resulting evidence report and other sources of data were used to formulate the practice guideline recommendations.

The focus of this practice guideline is the appropriate diagnosis and initial treatment of a child presenting with AOM. The guideline provides a specific, stringent definition of AOM. It addresses pain management, initial observation versus antibiotic treatment, appropriate choices of antibiotic agents, and preventive measures. It also addresses recurrent AOM, which was not included in the 2004 guideline. Decisions were made on the basis of a systematic grading of the quality of evidence and benefit-harm relationships.

The practice guideline underwent comprehensive peer review before formal approval by the AAP.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with AOM. Rather, it is intended to assist primary care clinicians by providing a framework for clinical decision-making. It is not intended to replace clinical judgment or establish a protocol for all children with this condition. These recommendations may not provide the only appropriate approach to the management of this problem. *Pediatrics* 2013;131:e964–e999

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KEY WORDS

acute otitis media, otitis media, otoscopy, otitis media with effusion, watchful waiting, antibiotics, antibiotic prophylaxis, tympanostomy tube insertion, immunization, breastfeeding

ABBREVIATIONS

AAFP—American Academy of Family Physicians
 AAP—American Academy of Pediatrics
 AHRQ—Agency for Healthcare Research and Quality
 AOM—acute otitis media
 CI—confidence interval
 FDA—US Food and Drug Administration
 LAIV—live-attenuated intranasal influenza vaccine
 MEE—middle ear effusion
 MIC—minimum inhibitory concentration
 NNT—number needed to treat
 OM—otitis media
 OME—otitis media with effusion
 OR—odds ratio
 PCV7—heptavalent pneumococcal conjugate vaccine
 PCV13—13-valent pneumococcal conjugate vaccine
 RD—rate difference
 SNAP—safety-net antibiotic prescription
 TIV—trivalent inactivated influenza vaccine
 TM—tympanic membrane
 WASP—wait-and-see prescription

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

(Continued on last page)

Key Action Statement 1A: Clinicians should diagnose acute otitis media (AOM) in children who present with moderate to severe bulging of the tympanic membrane (TM) *or* new onset of otorrhea not due to acute otitis externa. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 1B: Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) *or* intense erythema of the TM. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 1C: Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 2: The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3A: Severe AOM: The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia *or* otalgia for at least 48 hours *or* temperature 39°C [102.2°F] *or* higher). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3B: Non-severe bilateral AOM in young children: The clinician should prescribe antibiotic therapy for bilateral AOM in children 6 months through 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and

temperature less than 39°C [102.2°F]). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3C: Non-severe unilateral AOM in young children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens *or* fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3D: Nonsevere AOM in older children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens *or* fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4A: Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic

to penicillin. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4B: Clinicians should prescribe an antibiotic with additional β -lactamase coverage for AOM when a decision to treat with antibiotics has been made, *and* the child has received amoxicillin in the last 30 days *or* has concurrent purulent conjunctivitis, *or* has a history of recurrent AOM unresponsive to amoxicillin. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 4C: Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened *or* failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5A: Clinicians should not prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5B: Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months *or* 4 episodes in 1 year with 1 episode in the preceding 6 months). Evidence Quality: Grade B. Strength: Option.

Key Action Statement 6A: Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 6B: Clinicians should recommend annual influenza vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. Evidence Quality: Grade B. Strength: Recommendation.

2Key Action Statement 6C: Clinicians should encourage exclusive breastfeeding for at least 6 months. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 6D: Clinicians should encourage avoidance of tobacco smoke exposure. Evidence Quality: Grade C. Strength: Recommendation.

INTRODUCTION

In May 2004, the AAP and AAFP published the "Clinical Practice Guideline: Diagnosis and Management of Acute Otitis Media".¹ The guideline offered 8 recommendations ranked according to level of evidence and benefit-harm relationship. Three of the recommendations—diagnostic criteria, observation, and choice of antibiotics—led to significant discussion, especially among experts in the field of otitis media (OM). Also, at the time the guideline was written, information regarding the heptavalent pneumococcal conjugate vaccine (PCV7) was not yet published. Since completion of the guideline in November 2003 and its publication in May 2004, there has been a significant body of additional literature on AOM.

Although OM remains the most common condition for which antibacterial agents are prescribed for children in the United States^{2,3} clinician visits for OM decreased from 950 per 1000 children in 1995–1996 to 634 per 1000 children in 2005–2006. There has been a proportional decrease in antibiotic prescriptions for OM from 760 per 1000 in 1995–1996 to 484 per 1000 in 2005–2006. The percentage of OM visits

resulting in antibiotic prescriptions remained relatively stable (80% in 1995–1996; 76% in 2005–2006).² Many factors may have contributed to the decrease in visits for OM, including financial issues relating to insurance, such as copayments, that may limit doctor visits, public education campaigns regarding the viral nature of most infectious diseases, use of the PCV7 pneumococcal vaccine, and increased use of the influenza vaccine. Clinicians may also be more attentive to differentiating AOM from OM with effusion (OME), resulting in fewer visits coded for AOM and fewer antibiotic prescriptions written.

Despite significant publicity and awareness of the 2004 AOM guideline, evidence shows that clinicians are hesitant to follow the guideline recommendations. Vernacchio et al⁴ surveyed 489 primary care physicians as to their management of 4 AOM scenarios addressed in the 2004 guideline. No significant changes in practice were noted on this survey, compared with a survey administered before the 2004 AOM guideline. Coco⁵ used the National Ambulatory Medical Care Survey from 2002 through 2006 to determine the frequency of AOM visits without antibiotics before and after publication of the 2004 guideline. There was no difference in prescribing rates. A similar response to otitis guidelines was found in Italy as in the United States.^{6,7} These findings parallel results of other investigations regarding clinician awareness and adherence to guideline recommendations in all specialties, including pediatrics.⁸ Clearly, for clinical practice guidelines to be effective, more must be done to improve their dissemination and implementation.

This revision and update of the AAP/AAFP 2004 AOM guideline¹ will evaluate published evidence on the diagnosis and management of uncomplicated AOM and make recommendations based on that evidence. The guideline is intended

for primary care clinicians including pediatricians and family physicians, emergency department physicians, otolaryngologists, physician assistants, and nurse practitioners. The scope of the guideline is the diagnosis and management of AOM, including recurrent AOM, in children 6 months through 12 years of age. It applies only to an otherwise healthy child without underlying conditions that may alter the natural course of AOM, including but not limited to the presence of tympanostomy tubes; anatomic abnormalities, including cleft palate; genetic conditions with craniofacial abnormalities, such as Down syndrome; immune deficiencies; and the presence of cochlear implants. Children with OME without AOM are also excluded.

Glossary of Terms

AOM—the rapid onset of signs and symptoms of inflammation in the middle ear^{9,10}

Uncomplicated AOM—AOM without otorrhea¹

Severe AOM—AOM with the presence of moderate to severe otalgia *or* fever equal to or higher than 39°C^{9,10}

Nonsevere AOM—AOM with the presence of mild otalgia and a temperature below 39°C^{9,10}

Recurrent AOM—3 or more well-documented and separate AOM episodes in the preceding 6 months *or* 4 or more episodes in the preceding 12 months with at least 1 episode in the past 6 months^{11,12}

OME—inflammation of the middle ear with liquid collected in the middle ear; the signs and symptoms of acute infection are absent⁹

MEE—liquid in the middle ear without reference to etiology, pathogenesis, pathology, or duration⁹

Otorrhea—discharge from the ear, originating at 1 or more of the following sites: the external auditory canal,

middle ear, mastoid, inner ear, or intracranial cavity

Otitis externa—an infection of the external auditory canal

Tympanometry—measuring acoustic immittance (transfer of acoustic energy) of the ear as a function of ear canal air pressure^{13,14}

Number needed to treat (NNT)—the number of patients who need to be treated to prevent 1 additional bad outcome¹⁵

Initial antibiotic therapy—treatment of AOM with antibiotics that are prescribed at the time of diagnosis with the intent of starting antibiotic therapy as soon as possible after the encounter

Initial observation—initial management of AOM limited to symptomatic relief, with commencement of antibiotic therapy only if the child's condition worsens at any time or does not show clinical improvement within 48 to 72 hours of diagnosis; a mechanism must be in place to ensure follow-up and initiation of antibiotics if the child fails observation

METHODS

Guideline development using an evidence-based approach requires that all evidence related to the guideline is gathered in a systematic fashion, objectively assessed, and then described so readers can easily see the links between the evidence and recommendations made. An evidence-based approach leads to recommendations that are guided by both the quality of the available evidence and the benefit-to-harm ratio that results from following the recommendation. Figure 1 shows the relationship of evidence quality and benefit-harm balance in determining the level of recommendation. Table 1 presents the AAP definitions and implications of different levels of evidence-based recommendations.¹⁶

In preparing for the 2004 AAP guidelines, the Agency for Healthcare Research and Quality (AHRQ) funded and conducted an exhaustive review of the literature on diagnosis and management of AOM.^{17–19} In 2008, the AHRQ and the Southern California Evidence-Based Practice Center began a similar process of reviewing the literature published since the 2001 AHRQ report. The AAP again partnered with AHRQ and the Southern California Evidence-Based Practice Center to develop the evidence report, which served as a major source of data for these practice guideline recommendations.^{20,21} New key questions were determined by a technical expert panel. The scope of the new report went beyond the 2001 AHRQ report to include recurrent AOM.

The key questions addressed by AHRQ in the 2010 report were as follows:

1. Diagnosis of AOM: What are the operating characteristics (sensitivity, specificity, and likelihood ratios) of clinical symptoms and otoscopic findings (such as bulging TM) to diagnose uncomplicated AOM and to distinguish it from OME?
2. What has been the effect of the use of heptavalent PCV7 on AOM microbial epidemiology, what organisms (bacterial and viral) are associated with AOM since the introduction of PCV7, and what are the patterns

of antimicrobial resistance in AOM since the introduction of PCV7?

3. What is the comparative effectiveness of various treatment options for treating uncomplicated AOM in average risk children?
4. What is the comparative effectiveness of different management options for recurrent OM (uncomplicated) and persistent OM or relapse of AOM?
5. Do treatment outcomes in Questions 3 and 4 differ by characteristics of the condition (AOM), patient, environment, and/or health care delivery system?
6. What adverse effects have been observed for treatments for which outcomes are addressed in Questions 3 and 4?

For the 2010 review, searches of PubMed and the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center were conducted by using the same search strategies used for the 2001 report for publications from 1998 through June 2010. Additional terms or conditions not considered in the 2001 review (recurrent OM, new drugs, and heptavalent pneumococcal vaccine) were also included. The Web of Science was also used to search for citations of the 2001 report and its peer-reviewed publications. Titles were screened independently by 2

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs* or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation Recommendation	

FIGURE 1

Relationship of evidence quality and benefit-harm balance in determining the level of recommendation. RCT, randomized controlled trial.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No Recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

pediatricians with experience in conducting systematic reviews.

For the question pertaining to diagnosis, efficacy, and safety, the search was primarily for clinical trials. For the question pertaining to the effect of PCV7 on epidemiology and microbiology, the group searched for trials that compared microbiology in the same populations before and after introduction of the vaccine or observational studies that compared microbiology across vaccinated and unvaccinated populations.

In total, the reviewers examined 7646 titles, of which 686 titles were identified for further review. Of those, 72 articles that met the predetermined inclusion and exclusion criteria were reviewed in detail. Investigators abstracted data into standard evidence tables, with accuracy checked by a second investigator. Studies were quality-rated by 2 investigators by using established criteria. For randomized controlled trials, the Jadad criteria were used.²² QUADAS criteria²³ were used to evaluate the studies that pertained to diagnosis. GRADE criteria were applied to pooled analyses.²⁴ Data abstracted

included parameters necessary to define study groups, inclusion/exclusion criteria, influencing factors, and outcome measures. Some of the data for analysis were abstracted by a biostatistician and checked by a physician reviewer. A sequential resolution strategy was used to match and resolve the screening and review results of the 2 pediatrician reviewers.

For the assessment of treatment efficacy, pooled analyses were performed for comparisons for which 3 or more trials could be identified. Studies eligible for analyses of questions pertaining to treatment efficacy were grouped for comparisons by treatment options. Each comparison consisted of studies that were considered homogeneous across clinical practice. Because some of the key questions were addressed in the 2001 evidence report,¹⁷ studies identified in that report were included with newly identified articles in the 2010 evidence report.²⁰

Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations as well as expert consensus when

definitive data were not available. Results of the literature review were presented in evidence tables and published in the final evidence report.²⁰

In June 2009, the AAP convened a new subcommittee to review and revise the May 2004 AOM guideline.¹ The subcommittee comprised primary care physicians and experts in the fields of pediatrics, family practice, otolaryngology, epidemiology, infectious disease, emergency medicine, and guideline methodology. All panel members reviewed the AAP policy on conflict of interest and voluntary disclosure and were given an opportunity to present any potential conflicts with the subcommittee's work. All potential conflicts of interest are listed at the end of this document. The project was funded by the AAP. New literature on OM is continually being published. Although the systematic review performed by AHRQ could not be replicated with new literature, members of the Subcommittee on Diagnosis and Management of Acute Otitis Media reviewed additional articles. PubMed was searched by using the single search term "acute otitis media,"

approximately every 6 months from June 2009 through October 2011 to obtain new articles. Subcommittee members evaluated pertinent articles for quality of methodology and importance of results. Selected articles used in the AHRQ review were also reevaluated for their quality. Conclusions were based on the consensus of the subcommittee after the review of newer literature and reevaluation of the AHRQ evidence. Key action statements were generated using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements.²⁵ BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

After thorough review by the subcommittee for this guideline, a draft was reviewed by other AAP committees and sections, selected outside organizations, and individuals identified by the subcommittee as experts in the field. Additionally, members of the subcommittee were encouraged to distribute the draft to interested parties in their respective specialties. All comments were reviewed by the writing group and incorporated into the final guideline when appropriate.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with AOM. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or establish a protocol for the care of all children with this condition. These recommendations may not provide the only appropriate approach to the management of children with AOM.

It is AAP policy to review and update evidence-based guidelines every 5 years.

KEY ACTION STATEMENTS

Key Action Statement 1A

Clinicians should diagnose AOM in children who present with moderate

to severe bulging of the TM or new onset of otorrhea not due to acute otitis externa. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1A

Aggregate evidence quality	Grade B
Benefits	- Identify a population of children most likely to benefit from intervention. - Avoid unnecessary treatment of those without highly certain AOM. - Promote consistency in diagnosis.
Risks, harms, cost	May miss AOM that presents with a combination of mild bulging, intense erythema, or otalgia that may not necessarily represent less severe disease and may also benefit from intervention.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Identification of a population of children with highly certain AOM is beneficial. Accurate, specific diagnosis is helpful to the individual patient. Modification of current behavior of overdiagnosis is a goal. Increased specificity is preferred even as sensitivity is lowered.
Intentional vagueness	By using stringent diagnostic criteria, the TM appearance of less severe illness that might be early AOM has not been addressed.
Role of patient preferences	None
Exclusions	None
Strength	Recommendation
Notes	Tympanocentesis studies confirm that using these diagnostic findings leads to high levels of isolation of pathogenic bacteria. Evidence is extrapolated from treatment studies that included tympanocentesis.

Key Action Statement 1B

Clinicians should diagnose AOM in children who present with mild bulging of the TM and recent (less than 48 hours) onset of ear pain

(holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1B

Aggregate evidence quality	Grade C
Benefits	Identify AOM in children when the diagnosis is not highly certain.
Risks, harms, cost	Overdiagnosis of AOM. Reduced precision in diagnosis.
Benefits-harms assessment	Benefits greater than harms.
Value judgments	None.
Intentional vagueness	Criteria may be more subjective.
Role of patient preferences	None
Exclusions	None
Strength	Recommendation
Notes	Recent onset of ear pain means within the past 48 hours.

Key Action Statement 1C

Clinicians should not diagnose AOM in children who do not have MEE (based on pneumatic otoscopy and/or tympanometry). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1C	
Aggregate evidence quality	Grade B
Benefits	Reduces overdiagnosis and unnecessary treatment. Increases correct diagnosis of other conditions with symptoms that otherwise might be attributed to AOM. Promotes the use of pneumatic otoscopy and tympanometry to improve diagnostic accuracy.
Risks, harms, cost	Cost of tympanometry. Need to acquire or reacquire skills in pneumatic otoscopy and tympanometry for some clinicians.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	AOM is overdiagnosed, often without adequate visualization of the TM. Early AOM without effusion occurs, but the risk of overdiagnosis supersedes that concern.
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Early AOM evidenced by intense erythema of the TM.
Strength	Recommendation

Purpose of This Section

There is no gold standard for the diagnosis of AOM. In fact, AOM has a spectrum of signs as the disease develops.²⁶ Therefore, the purpose of this section is to provide clinicians and researchers with a working clinical definition of AOM and to differentiate AOM from OME. The criteria were chosen to achieve high specificity recognizing that the resulting decreased sensitivity may exclude less severe presentations of AOM.

Changes From AAP/AAPF 2004 AOM Guideline

Accurate diagnosis of AOM is critical to sound clinical decision-making and high-quality research. The 2004 “Clinical Practice Guideline: Diagnosis and Management of AOM”¹ used a 3-part definition for AOM: (1) acute onset of symptoms, (2) presence of MEE, and (3) signs of acute middle ear inflammation. This definition generated extensive discussion and reanalysis of the AOM diagnostic evidence. The 2004 definition lacked precision to exclude cases of OME, and diagnoses of AOM

could be made in children with acute onset of symptoms, including severe otalgia and MEE, without other otoscopic findings of inflammation.²⁷ Furthermore, the use of “uncertain diagnosis” in the 2004 AOM guideline may have permitted diagnoses of AOM without clear visualization of the TM. Earlier studies may have enrolled children who had OME rather than AOM, resulting in the possible classification of such children as improved because their nonspecific symptoms would have abated regardless of therapy.^{28–30} Two studies, published in 2011, used stringent diagnostic criteria for diagnosing AOM with much less risk of conclusions based on data from mixed patients.^{31,32}

Since publication of the 2004 AOM guideline, a number of studies have been conducted evaluating scales for the presence of symptoms. These studies did not show a consistent correlation of symptoms with the initial diagnosis of AOM, especially in preverbal children.^{33–35}

Recent research has used precisely stated stringent criteria of AOM for

purposes of the studies.^{31,32} The current guideline endorses stringent otoscopic diagnostic criteria as a basis for management decisions (described later). As clinicians use the proposed stringent criteria to diagnose AOM, they should be aware that children with AOM may also present with recent onset of ear pain and intense erythema of the TM as the only otoscopic finding.

Symptoms

Older children with AOM usually present with a history of rapid onset of ear pain. However, in young preverbal children, otalgia as suggested by tugging/rubbing/holding of the ear, excessive crying, fever, or changes in the child’s sleep or behavior pattern as noted by the parent are often relatively nonspecific symptoms. A number of studies have attempted to correlate symptom scores with diagnoses of AOM.

A systematic review³⁶ identified 4 articles that evaluated the accuracy of symptoms.^{37–40} Ear pain appeared useful in diagnosing AOM (combined positive likelihood ratio 3.0–7.3, negative likelihood ratio 0.4–0.6); however, it was only present in 50% to 60% of children with AOM. Conclusions from these studies may be limited, because they (1) enrolled children seen by specialists, not likely to represent the whole spectrum of severity of illness; (2) used a clinical diagnosis of AOM based more on symptomatology rather than on tympanocentesis; and (3) included relatively older children.^{37,40}

Laine et al³⁴ used a questionnaire administered to 469 parents who suspected their children, aged 6 to 35 months, had AOM. Of the children, 237 had AOM using strict otoscopic criteria, and 232 had upper respiratory tract infection without AOM. Restless sleep, ear rubbing, fever, and non-specific respiratory or gastrointestinal

tract symptoms did not differentiate children with or without AOM.

McCormick et al³⁰ used 2 symptom scores—a 3-item score (OM-3), consisting of symptoms of physical suffering such as ear pain or fever, emotional distress (irritability, poor appetite), and limitation in activity; and a 5-item score (Ear Treatment Group Symptom Questionnaire, 5 Items [ETG-5]), including fever, earache, irritability, decreased appetite, and sleep disturbance—to assess AOM symptoms at the time of diagnosis and daily during the 10-day treatment or observation period. They found both to be a responsive measure of changes in clinical symptoms. The same group³⁵ also tested a visual scale, Acute Otitis Media-Faces Scale (AOM-FS), with faces similar to the Wong-Baker pain scale.⁴¹ None of the scales were adequately sensitive for making the diagnosis of AOM based on symptoms. The AOM-FS combined with an otoscopy score, OS-8,³⁰ were presented as a double-sided pocket card. The combination of AOM-FS and OS-8 was more responsive to change than either instrument alone.

Shaikh et al^{33,42} validated a 7-item parent-reported symptom score (Acute Otitis Media Severity of Symptom Scale [AOM-SOS]) for children with AOM, following stringent guidance of the US Food and Drug Administration (FDA) on the development of patient-reported outcome scales. Symptoms included ear tugging/rubbing/holding, excessive crying, irritability, difficulty sleeping, decreased activity or appetite, and fever. AOM-SOS was correlated with otoscopic diagnoses (AOM, OME, and normal middle ear status). AOM-SOS changed appropriately in response to clinical change. Its day-to-day responsiveness supports its usefulness in following AOM symptoms over time.

Signs of AOM

Few studies have evaluated the relationship of otoscopic findings in AOM

and tympanocentesis. A study by Karma et al⁴³ is often cited as the best single study of otoscopic findings in AOM. However, the study uses only a symptom-based diagnosis of AOM plus the presence of MEE. Thus, children with acute upper respiratory tract infection symptoms and OME would have been considered to have AOM. There also were significant differences in findings at the 2 centers that participated in the study.

The investigators correlated TM color, mobility, and position with the presence of middle ear fluid obtained by tympanocentesis. At 2 sites in Finland (Tampere and Oulu), 2911 children were followed from 6 months to 2.5 years of age. A single otolaryngologist at Tampere and a single pediatrician at Oulu examined subjects. Color, position, and mobility were recorded. Myringotomy and aspiration were performed if MEE was suspected. AOM was diagnosed if MEE was found and the child had fever, earache, irritability, ear rubbing or tugging, simultaneous other acute respiratory tract symptoms, vomiting, or diarrhea. The presence or absence of MEE was noted, but no analyses of the fluid, including culture, were performed. Pneumatic otoscopic findings were classified as follows: color—hemorrhagic, strongly red, moderately red, cloudy or dull, slightly red, or normal; position—bulging, retracted, or normal; and mobility—distinctly impaired, slightly impaired, or normal.

For this analysis, 11 804 visits were available. For visits with acute symptoms, MEE was found in 84.9% and 81.8% at the 2 sites at which the study was performed. There were significant differences among the results at the 2 centers involved in the study. Table 2 shows specific data for each finding.

The combination of a “cloudy,” bulging TM with impaired mobility was the

TABLE 2 Otoscope Findings in Children With Acute Symptoms and MEE^a

TM Finding in Acute Visits With MEE	Group I (Tampere, Finland), %	Group II (Oulu, Finland), %
Color		
Distinctly red	69.8	65.6
Hemorrhagic	81.3	62.9
Strongly red	87.7	68.1
Moderately red	59.8	66.0
Slightly red	39.4	16.7
Cloudy	95.7	80.0
Normal	1.7	4.9
Position		
Bulging	96.0	89
Retracted	46.8	48.6
Normal	32.1	22.2
Mobility		
Distinctly impaired	94.0	78.5
Slightly impaired	59.7	32.8
Normal	2.7	4.8

^a Totals are greater than 100%, because each ear may have had different findings.⁴³

best predictor of AOM using the symptom-based diagnosis in this study. Impaired mobility had the highest sensitivity and specificity (approximately 95% and 85%, respectively). Cloudiness had the next best combination of high sensitivity (~74%) and high specificity (~93%) in this study. Bulging had high specificity (~97%) but lower sensitivity (~51%). A TM that was hemorrhagic, strongly red, or moderately red also correlated with the presence of AOM, and a TM that was only “slightly red” was not helpful diagnostically.

McCormick et al reported that a bulging TM was highly associated with the presence of a bacterial pathogen, with or without a concomitant viral pathogen.⁴⁴ In a small study, 31 children (40 ears) underwent myringotomy.⁴⁵ Bulging TMs had positive bacterial cultures 75% of the time. The percentage of positive cultures for a pathogen increased to 80% if the color of the TM was yellow. The conclusion is that moderate to severe bulging of the TM represents the most important characteristic in the diagnosis of AOM—a finding that has

implications for clinical care, research, and education.

The committee recognized that there is a progression from the presence of MEE to the bulging of the TM, and it is often difficult to differentiate this equivocal appearance from the highly certain AOM criteria advocated in this guideline.²⁶ As such, there is a role for individualized diagnosis and management decisions. Examples of normal, mild bulging, moderate bulging, and severe bulging can be seen in Fig 2.

Distinguishing AOM From OME

OME may occur either as the aftermath of an episode of AOM or as a consequence of eustachian tube dysfunction attributable to an upper respiratory tract infection.⁴⁶ However, OME may also precede and predispose to the development of AOM. These 2 forms of OM may be considered segments of a disease continuum.⁴⁷ However, because OME does not represent an acute infectious process that benefits from antibiotics, it is of utmost importance for clinicians to become proficient in distinguishing normal middle ear status from OME or AOM. Doing so will avoid unnecessary use of antibiotics, which leads to increased adverse effects of medication and facilitates the development of antimicrobial resistance.

Examination of the TM

Accurate diagnosis of AOM in infants and young children may be difficult.

Symptoms may be mild or overlap with those of an upper respiratory tract illness. The TM may be obscured by cerumen, and subtle changes in the TM may be difficult to discern. Additional factors complicating diagnosis may include lack of cooperation from the child; less than optimal diagnostic equipment, including lack of a pneumatic bulb; inadequate instruments for clearing cerumen from the external auditory canal; inadequate assistance for restraining the child; and lack of experience in removing cerumen and performing pneumatic otoscopy.

The pneumatic otoscope is the standard tool used in diagnosing OM. Valuable also is a surgical head, which greatly facilitates cleaning cerumen from an infant's external auditory canal. Cerumen may be removed by using a curette, gentle suction, or irrigation.⁴⁸ The pneumatic otoscope should have a light source of sufficient brightness and an air-tight seal that permits application of positive and negative pressure. In general, nondisposable specula achieve a better seal with less pain because of a thicker, smoother edge and better light transmission properties. The speculum size should be chosen to gently seal at the outer portion of the external auditory canal.

Pneumatic otoscopy permits assessment of the contour of the TM (normal, retracted, full, bulging), its color (gray, yellow, pink, amber, white, red, blue), its translucency (translucent,

semiopaque, opaque), and its mobility (normal, increased, decreased, absent). The normal TM is translucent, pearly gray, and has a ground-glass appearance (Fig 2A). Specific landmarks can be visualized. They include the short process and the manubrium of the malleus and the pars flaccida, located superiorly. These are easily observed and help to identify the position of the TM. Inward movement of the TM on positive pressure in the external canal and outward movement on negative pressure should occur, especially in the superior posterior quadrant. When the TM is retracted, the short process of the malleus becomes more prominent, and the manubrium appears shortened because of its change in position within the middle ear. Inward motion occurring with positive pressure is restricted or absent, because the TM is frequently as far inward as its range of motion allows. However, outward mobility can be visualized when negative pressure is applied. If the TM does not move perceptibly with applications of gentle positive or negative pressure, MEE is likely. Sometimes, the application of pressure will make an air-fluid interface behind the TM (which is diagnostic of MEE) more evident.⁴⁹

Instruction in the proper evaluation of the child's middle ear status should begin with the first pediatric rotation in medical school and continue throughout postgraduate training.⁵⁰

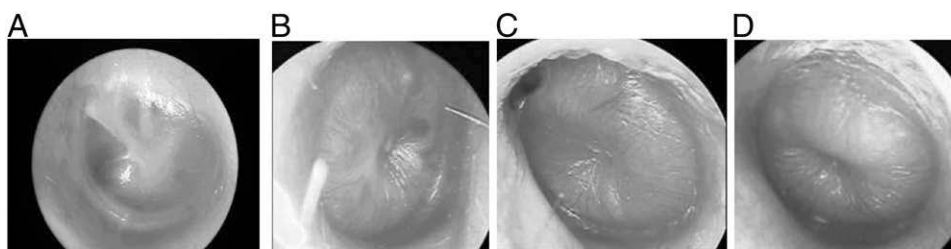


FIGURE 2

A, Normal TM. B, TM with mild bulging. C, TM with moderate bulging. D, TM with severe bulging. Courtesy of Alejandro Hoberman, MD.

Continuing medical education should reinforce the importance of, and retrain the clinician in, the use of pneumatic otoscopy.⁵¹ Training tools include the use of a video-otoscope in residency programs, the use of Web-based educational resources,^{49,52} as well as simultaneous or sequential examination of TMs with an expert otoscopist to validate findings by using a double headed or video otoscope. Tools for learning the ear examination can be found in a CD distributed by the Johns Hopkins University School of Medicine and the Institute for Johns

Hopkins Nursing,⁵³ also available at <http://www2.aap.org/sections/infectdis/video.cfm>,⁵⁴ and through a Web-based program, ePROM: Enhancing Proficiency in Otitis Media.⁵²

Key Action Statement 2

The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 2

Aggregate evidence quality	Grade B
Benefits	Relieves the major symptom of AOM.
Risks, harms, cost	Potential medication adverse effects. Variable efficacy of some modes of treatment.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Treating pain is essential whether or not antibiotics are prescribed.
Intentional vagueness	Choice of analgesic is not specified.
Role of patient preferences	Parents may assist in the decision as to what means of pain relief they prefer.
Exclusions	Topical analgesics in the presence of a perforated TM.
Strength	Strong Recommendation

Purpose of This Section

Pain is the major symptom of AOM. This section addresses and updates the literature on treating otalgia.

Changes From AAP/AAPF 2004 AOM Guideline

Only 2 new articles directly address the treatment of otalgia. Both address topical treatment. The 2 new articles are consistent with the 2004 guideline statement. The text of the 2004 guideline is, therefore, reproduced here, with the addition of discussion of the 2 new articles. Table 3 has been updated to include the new references.

Treatment of Otalgia

Many episodes of AOM are associated with pain.⁵⁵ Some children with OME also have ear pain. Although pain is

a common symptom in these illnesses, clinicians often see otalgia as a peripheral concern not requiring direct attention.⁵⁶ Pain associated

with AOM can be substantial in the first few days of illness and often persists longer in young children.⁵⁷ Antibiotic therapy of AOM does not provide symptomatic relief in the first 24 hours^{58–61} and even after 3 to 7 days, there may be persistent pain, fever, or both in 30% of children younger than 2 years.⁶² In contrast, analgesics do relieve pain associated with AOM within 24 hours⁶³ and should be used whether antibiotic therapy is or is not prescribed; they should be continued as long as needed. The AAP published the policy statement “The Assessment and Management of Acute Pain in Infants, Children, and Adolescents”⁶⁴ to assist the clinician in addressing pain in the context of illness. The management of pain, especially during the first 24 hours of an episode of AOM, should be addressed regardless of the use of antibiotics.

Various treatments of otalgia have been used, but none has been well studied. The clinician should select a treatment on the basis of a consideration of benefits and risks and, wherever possible, incorporate parent/caregiver and patient preference (Table 3).

TABLE 3 Treatments for Otalgia in AOM

Treatment Modality	Comments
Acetaminophen, ibuprofen ⁶³	Effective analgesia for mild to moderate pain. Readily available. Mainstay of pain management for AOM.
Home remedies (no controlled studies that directly address effectiveness)	May have limited effectiveness.
Distraction	
External application of heat or cold	
Oil drops in external auditory canal	
Topical agents	
Benzocaine, procaine, lidocaine ^{65,67,70}	Additional, but brief, benefit over acetaminophen in patients older than 5 y.
Naturopathic agents ⁶⁸	Comparable to amethocaine/phenazone drops in patients older than 6 y.
Homeopathic agents ^{71,72}	No controlled studies that directly address pain.
Narcotic analgesia with codeine or analogs	Effective for moderate or severe pain. Requires prescription; risk of respiratory depression, altered mental status, gastrointestinal tract upset, and constipation.
Tympanostomy/myringotomy ⁷³	Requires skill and entails potential risk.

Since the 2004 guideline was published, there have been only 2 significant new articles.

Bolt et al reported in 2008 on a double-blind placebo-controlled trial at the Australia Children's Hospital emergency department conducted in 2003–2004.⁶⁵ They used a convenience sample of children 3 to 17 years of age diagnosed with AOM in the ED. They excluded children with perforation of the TM, pressure-equalizing tube, allergy to local anesthetic or paracetamol, epilepsy, or liver, renal, or cardiac disease. Sixty-three eligible children were randomized to receive aqueous lidocaine or normal saline ear drops up to 3 times in 24 hours. They demonstrated a statistically significant 50% reduction in reported pain at 10 and 30 minutes but not at 20 minutes after application of topical lidocaine, compared with normal saline. Complications were minimal: 3 children reported some dizziness the next day, and none reported tinnitus. A limitation was that some children had received oral acetaminophen before administration of ear drops.

A Cochrane review of topical analgesia for AOM⁶⁶ searched the Cochrane register of controlled trials, randomized controlled trials, or quasi-randomized controlled trials that compared otic preparations to placebo or that compared 2 otic preparations. It included studies of adults and children, without TM perforation.

It identified 5 trials in children 3 to 18 years of age. Two (including Bolt et al,⁶⁵ discussed above) compared anesthetic drops and placebo at diagnosis of AOM. In both studies, some children also received oral analgesics. Three studies compared anesthetic ear drops with naturopathic herbal drops. Naturopathic drops were favored 15 to 30 minutes after installation, and 1 to 3 days after diagnosis, but the difference was not statistically significant. The Cochrane group concluded that there is limited evidence that ear drops are effective at 30 minutes and unclear if results from these studies are a result of the natural course of illness, placebo effect of receiving treatment, soothing effect of any liquid in the ear, or the drops themselves. Three of the studies included in this review were cited in the 2004 AAP guideline^{67–69} and the 1 new paper by Bolt et al.⁶⁵

Key Action Statement 3A

Severe AOM

The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours, or temperature 39°C [102.2°F] or higher). (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 3A

Aggregate evidence quality	Grade B
Benefits	Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	None
Role of patient preference	None
Intentional vagueness	None
Exclusions	None
Strength	Strong Recommendation

Key Action Statement 3B

Nonsevere Bilateral AOM in Young Children

The clinician should prescribe antibiotic therapy for bilateral AOM in children younger than 24 months without severe signs or symptoms (ie, mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS

Aggregate evidence quality	Grade B
Benefits	Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	None
Role of patient preference	None
Intentional vagueness	None
Exclusions	None
Strength	Recommendation

Key Action Statement 3C

Nonsevere Unilateral AOM in Young Children

The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure

follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of

onset of symptoms. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 3C

Aggregate evidence quality	Grade B
Benefits	Moderately increased likelihood of more rapid resolution of symptoms with initial antibiotics. Moderately increased likelihood of resolution of AOM with initial antibiotics.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Moderate degree of benefit over harm.
Value judgments	Observation becomes an alternative as the benefits and harms approach balance.
Role of patient preference	Joint decision-making with the family is essential before choosing observation.
Intentional vagueness	Joint decision-making is highly variable from family to family
Exclusions	None
Strength	Recommendation
Note	In the judgment of 1 Subcommittee member (AH), antimicrobial treatment of these children is preferred because of a preponderance of benefit over harm. AH did not endorse Key Action Statement 3C

Key Action Statement 3D

Nonsevere AOM in Older Children

The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia

for less than 48 hours, temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Rec Strength: Recommendation)

Key Action Statement Profile: KAS 3D

Aggregate evidence quality	Grade B
Benefits	<i>Initial antibiotic treatment:</i> Slightly increased likelihood of more rapid resolution of symptoms; slightly increased likelihood of resolution of AOM. <i>Initial observation:</i> Decreased use of antibiotics; decreased adverse effects of antibiotics; decreased potential for development of bacterial resistance.
Risks, harms, cost	<i>Initial antibiotic treatment:</i> Adverse events attributable to antibiotics such as diarrhea, rashes, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. <i>Initial observation:</i> Possibility of needing to start antibiotics in 48 to 72 h if the patient continues to have symptoms. Minimal risk of adverse consequences of delayed antibiotic treatment. Potential increased phone calls and doctor visits.
Benefits-harms assessment	Slight degree of benefit of initial antibiotics over harm.
Value judgments	Observation is an option as the benefits and harms approach balance.
Role of patient preference	Joint decision-making with the family is essential before choosing observation.
Intentional vagueness	Joint decision-making is highly variable from family to family.
Exclusions	None
Strength	Recommendation.

Purpose of This Section

The purpose of this section is to offer guidance on the initial management of AOM by helping clinicians choose between the following 2 strategies:

1. *Initial antibiotic therapy*, defined as treatment of AOM with antibiotics that are prescribed at the time of diagnosis with the intent of starting antibiotic therapy as soon as possible after the encounter.
2. *Initial observation*, defined as initial management of AOM limited to symptomatic relief, with commencement of antibiotic therapy only if the child's condition worsens at any time or does not show clinical improvement within 48 to 72 hours of diagnosis. A mechanism must be in place to ensure follow-up and initiation of antibiotics if the child fails observation.

This section assumes that the clinician has made an accurate diagnosis of AOM by using the criteria and strategies outlined earlier in this guideline. Another assumption is that a clear distinction is made between the role of analgesics and antibiotics in providing symptomatic relief for children with AOM.

Changes From Previous AOM Guideline

The AOM guideline published by the AAP and AAFP in 2004 proposed, for the first time in North America, an "observation option" for selected children with AOM, building on successful implementation of a similar policy in the state of New York⁷⁴ and the use of a similar paradigm in many countries in Europe. A common feature of both approaches was to prioritize initial antibiotic therapy according to diagnostic certainty, with greater reliance on observation when the diagnosis was uncertain. In response to criticism that allowing an "uncertain

diagnosis” might condone incomplete visualization of the TM or allow inappropriate antibiotic use, this category has been eliminated with greater emphasis now placed on maximizing diagnostic accuracy for AOM.

Since the earlier AOM guideline was published, there has been substantial new research on initial management of AOM, including randomized controlled trials of antibiotic therapy versus placebo or no therapy,^{31,32,75} immediate versus delayed antibiotic therapy,^{30,76,77} or delayed antibiotic with or without a concurrent prescription.⁷⁸ The Hoberman and Tähtinen articles are especially important as they used stringent criteria for diagnosing AOM.^{31,32} Systematic reviews have been published on delayed antibiotic therapy,⁷⁹ the natural history of AOM in untreated children,⁵⁷ predictive factors for antibiotic benefits,⁶² and the effect of antibiotics on asymptomatic MEE after therapy.⁸⁰ Observational studies provide additional data on outcomes of initial observation with delayed antibiotic therapy, if needed,⁸¹ and on the relationship of previous antibiotic therapy for AOM to subsequent acute mastoiditis.^{82,83}

In contrast to the earlier AOM guideline,¹ which recommended antibiotic therapy for all children 6 months to 2 years of age with a certain diagnosis,

the current guideline indicates a choice between initial antibiotic therapy or initial observation in this age group for children with unilateral AOM and mild symptoms but only after joint decision-making with the parent(s)/caregiver (Table 4). This change is supported by evidence on the safety of observation or delayed prescribing in young children.^{30,31,32,75,76,81} A mechanism must be in place to ensure follow-up and begin antibiotics if the child fails observation.

Importance of Accurate Diagnosis

The recommendations for management of AOM assume an accurate diagnosis on the basis of criteria outlined in the diagnosis section of this guideline. Many of the studies since the 2004 AAP/AAFP AOM guideline¹ used more stringent and well-defined AOM diagnostic definitions than were previously used. Bulging of the TM was required for diagnosis of AOM for most of the children enrolled in the most recent studies.^{31,32} By using the criteria in this guideline, clinicians will more accurately distinguish AOM from OME. The management of OME can be found in guidelines written by the AAP, AAFP, and American Academy of Otolaryngology-Head and Neck Surgery.^{84,85}

Age, Severity of Symptoms, Otorrhea, and Laterality

Rovers et al⁶² performed a systematic search for AOM trials that (1) used random allocation of children, (2) included children 0 to 12 years of age with AOM, (3) compared antibiotics with placebo or no treatment, and (4) had pain or fever as an outcome. The original investigators were asked for their original data.

Primary outcome was pain and/or fever ($>38^{\circ}\text{C}$) at 3 to 7 days. The adverse effects of antibiotics were also analyzed. Baseline predictors were age <2 years versus ≥ 2 years, bilateral AOM versus unilateral AOM, and the presence versus absence of otorrhea. Statistical methods were used to assess heterogeneity and to analyze the data.

Of the 10 eligible studies, the investigators of 6 studies^{30,75,86–89} provided the original data requested, and 4 did not. A total of 1642 patients were included in the 6 studies from which data were obtained. Of the cases submitted, the average age was 3 to 4 years, with 35% of children younger than 2 years. Bilateral AOM was present in 34% of children, and 42% of children had a bulging TM. Otorrhea was present in 21% of children. The antibiotic and control groups were comparable for all characteristics.

The rate difference (RD) for pain, fever, or both between antibiotic and control groups was 13% (NNT = 8). For children younger than 2 years, the RD was 15% (NNT = 7); for those ≥ 2 years, RD was 11% (NNT = 10). For unilateral AOM, the RD was 6% (NNT = 17); for bilateral AOM, the RD was 20% (NNT = 5). When unilateral AOM was broken into age groups, among those younger than 2 years, the RD was 5% (NNT = 20), and among those ≥ 2 years, the RD was 7% (NNT = 15). For bilateral AOM in children younger than 2 years, the RD was 25% (NNT = 4); for

TABLE 4 Recommendations for Initial Management for Uncomplicated AOM^a

Age	Otorrhea With AOM ^a	Unilateral or Bilateral AOM ^a With Severe Symptoms ^b	Bilateral AOM ^a Without Otorrhea	Unilateral AOM ^a Without Otorrhea
6 mo to 2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation
≥ 2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation	Antibiotic therapy or additional observation ^c

^a Applies only to children with well-documented AOM with high certainty of diagnosis (see Diagnosis section).

^b A toxic-appearing child, persistent otalgia more than 48 h, temperature $\geq 39^{\circ}\text{C}$ (102.2°F) in the past 48 h, or if there is uncertain access to follow-up after the visit.

^c This plan of initial management provides an opportunity for shared decision-making with the child's family for those categories appropriate for additional observation. If observation is offered, a mechanism must be in place to ensure follow-up and begin antibiotics if the child worsens or fails to improve within 48 to 72 h of AOM onset.

bilateral AOM in children ≥ 2 years, the RD was 12% (NNT = 9). For otorrhea, the RD was 36% (NNT = 3). One child in the control group who developed meningitis had received antibiotics beginning on day 2 because of worsening status. There were no cases of mastoiditis.

In a Cochrane Review, Sanders et al⁵⁹ identified 10 studies that met the following criteria: (1) randomized controlled trial, (2) compared antibiotic versus placebo or antibiotic versus observation, (3) age 1 month to 15 years, (4) reported severity and duration of pain, (5) reported adverse events, and (6) reported serious complications of AOM, recurrent attacks, and hearing problems. Studies were analyzed for risk of bias and assessment of heterogeneity. The studies were the same as analyzed by Rovers et al⁶² but included the 4 studies for which primary data were not available to Rovers.^{60,61,90,91}

The authors' conclusions were that antibiotics produced a small reduction in the number of children with pain 2 to 7 days after diagnosis. They also concluded that most cases spontaneously remitted with no complications (NNT = 16). Antibiotics were most beneficial in children younger than 2 years with bilateral AOM and in children with otorrhea.

Two recent studies only included children younger than 3 years³² or younger than 2 years.³¹ Both included only subjects in whom the diagnosis of AOM was certain. Both studies used improvement of symptoms and improvement in the appearance of the TM in their definitions of clinical success or failure.

Hoberman et al³¹ conducted a randomized, double-blind, placebo-controlled study of the efficacy of antimicrobial treatment on AOM. The criteria for AOM were acute symptoms with a score of at least 3 on the AOM-SOS,

a validated symptom scale^{33,92}; MEE; and moderate or marked bulging of the TM or slight bulging accompanied by either otalgia or marked erythema of the TM. They chose to use high-dose amoxicillin-clavulanate (90 mg/kg/day) as active treatment, because it has the best oral antibiotic coverage for organisms causing AOM. Included in the study were 291 patients 6 to 23 months of age: 144 in the antibiotic group and 147 in the placebo group. The primary outcome measures were the time to resolution of symptoms and the symptom burden over time. The initial resolution of symptoms (ie, the first recording of an AOM-SOS score of 0 or 1) was recorded among the children who received amoxicillin-clavulanate in 35% by day 2, 61% by day 4, and 80% by day 7. Among children who received placebo, an AOM-SOS score of 0 or 1 was recorded in 28% by day 2, 54% by day 4, and 74% by day 7 ($P = .14$ for the overall comparison). For sustained resolution of symptoms (ie, the time to the second of 2 successive recordings of an AOM-SOS score of 0 or 1), the corresponding values were 20% at day 2, 41% at day 4, and 67% at day 7 with amoxicillin-clavulanate, compared with 14%, 36%, and 53% with placebo ($P = .04$ for the overall comparison). The symptom burden (ie, mean AOM-SOS scores) over the first 7 days were lower for the children treated with amoxicillin-clavulanate than for those who received placebo ($P = .02$). Clinical failure at or before the 4- to 5-day visit was defined as "either a lack of substantial improvement in symptoms, a worsening of signs on otoscopic examination, or both," and clinical failure at the 10- to 12-day visit was defined as "the failure to achieve complete or nearly complete resolution of symptoms and of otoscopic signs, without regard to the persistence or resolution of middle ear

effusion." Treatment failure occurred by day 4 to 5 in 4% of the antimicrobial treatment group versus 23% in the placebo group ($P < .001$) and at day 10 to 12 in 16% of the antimicrobial treatment group versus 51% in the placebo group (NNT = 2.9, $P < .001$). In a comparison of outcome in unilateral versus bilateral AOM, clinical failure rates by day 10 to 12 in children with unilateral AOM were 9% in those treated with amoxicillin-clavulanate versus 41% in those treated with placebo (RD, 32%; NNT = 3) and 23% vs 60% (RD, 37%; NNT = 3) in those with bilateral AOM. Most common adverse events were diarrhea (25% vs 15% in the treatment versus placebo groups, respectively; $P = .05$) and diaper dermatitis (51% vs 35% in the treatment versus placebo groups, respectively; $P = .008$). One placebo recipient developed mastoiditis. According to these results, antimicrobial treatment of AOM was more beneficial than in previous studies that used less stringent diagnostic criteria.

Tähtinen et al³² conducted a randomized, double-blind, placebo-controlled, intention-to-treat study of amoxicillin-clavulanate (40 mg/kg/day) versus placebo. Three hundred nineteen patients from 6 to 35 months of age were studied: 161 in the antibiotic group and 158 in the placebo group. AOM definition was the presence of MEE, distinct erythema over a bulging or yellow TM, and acute symptoms such as ear pain, fever, or respiratory symptoms. Compliance was measured by using daily patient diaries and number of capsules remaining at the end of the study. Primary outcome was time to treatment failure defined as a composite of 6 independent components: no improvement in overall condition by day 3, worsening of the child's condition at any time, no improvement in otoscopic signs by day 8, perforation of the TM,

development of severe infection (eg, pneumonia, mastoiditis), and any other reason for stopping the study drug/placebo.

Groups were comparable on multiple parameters. In the treatment group, 135 of 161 patients (84%) were younger than 24 months, and in the placebo group, 124 of 158 patients (78%) were younger than 24 months. Treatment failure occurred in 18.6% of the treatment group and 44.9% in the placebo group (NNT = 3.8, $P < .001$). Rescue treatment was needed in 6.8% of the treatment group and 33.5% of placebo patients ($P < .001$). Contralateral AOM developed in 8.2% and 18.6% of treatment and placebo groups, respectively ($P = .007$). There was no significant difference in use of analgesic or antipyretic medicine, which was used in 84.2% of the amoxicillin-clavulanate group and 85.9% of the placebo group.

Parents of child care attendees on placebo missed more days of work ($P = .005$). Clinical failure rates in children with unilateral AOM were 17.2% in those treated with amoxicillin-clavulanate versus 42.7% in those treated with placebo; for bilateral AOM, clinical failure rates were 21.7% for those treated with amoxicillin-clavulanate versus 46.3% in the placebo group. Reported rates of treatment failure by day 8 were 17.2% in the amoxicillin-clavulanate group versus 42.7% in the placebo group in children with unilateral AOM and 21.7% vs 46.3% among those with bilateral disease.

Adverse events, primarily diarrhea and/or rash, occurred in 52.8% of the treatment group and 36.1% of the placebo group ($P = .003$). Overall condition as evaluated by the parents and otoscopic appearance of the TM showed a benefit of antibiotics over placebo at the end of treatment visit ($P < .001$). Two placebo recipients

developed a severe infection; 1 developed pneumococcal bacteremia, and 1 developed radiographically confirmed pneumonia.

Most studies have excluded children with severe illness and all exclude those with bacterial disease other than AOM (pneumonia, mastoiditis, meningitis, streptococcal pharyngitis). Kaleida et al⁹¹ compared myringotomy alone with myringotomy plus antibiotics. Severe AOM was defined as temperature $>39^{\circ}\text{C}$ (102.2°F) or the presence of severe otalgia. Patients with severe AOM in the group that received only myringotomy (without initial antibiotics) had much worse outcomes.

Initial Antibiotic Therapy

The rationale for antibiotic therapy in children with AOM is based on a high prevalence of bacteria in the accompanying MEE.⁹³ Bacterial and viral cultures of middle ear fluid collected by tympanocentesis from children with AOM showed 55% with bacteria only and 15% with bacteria and viruses. A beneficial effect of antibiotics on AOM was first demonstrated in 1968,⁹⁴ followed by additional randomized trials and a meta-analysis⁹⁵ showing a 14% increase in absolute rates of clinical improvement. Systematic reviews of the literature published before 2011^{21,59,62} revealed increases of clinical improvement with initial antibiotics of 6% to 12%.

Randomized clinical trials using stringent diagnostic criteria for AOM in young children^{31,32} show differences in clinical improvement of 26% to 35% favoring initial antibiotic treatment as compared with placebo. Greater benefit of immediate antibiotic therapy was observed for bilateral AOM^{62,96} or AOM associated with otorrhea.⁶² In most randomized trials,^{30,75,77,88,89} antibiotic therapy also decreased the duration of pain, analgesic use, or

school absence and parent days missed from work.

Children younger than 2 years with AOM may take longer to improve clinically than older children,⁵⁷ and although they are more likely to benefit from antibiotics,^{31,32} AOM in many children will resolve without antibiotics.⁶² A clinically significant benefit of immediate antibiotic therapy is observed for bilateral AOM,^{62,96} *Streptococcus pneumoniae* infection, or AOM associated with otorrhea.⁶²

Initial Observation for AOM

In systematic reviews of studies that compare antibiotic therapy for AOM with placebo, a consistent finding has been the overall favorable natural history in control groups (NNT = 8–16).^{12,59,62,95} However, randomized trials in these reviews had varying diagnostic criteria that would have permitted inclusion of some children with OME, viral upper respiratory infections, or myringitis, thereby limiting the ability to apply these findings to children with a highly certain AOM diagnosis. In more recent AOM studies^{31,32} using stringent diagnostic criteria, approximately half of young children (younger than 2–3 years) experienced clinical success when given placebo, but the effect of antibiotic therapy was substantially greater than suggested by studies without precise diagnosis (NNT = 3–4).

Observation as initial management for AOM in properly selected children does not increase suppurative complications, provided that follow-up is ensured and a rescue antibiotic is given for persistent or worsening symptoms.¹⁷ In contrast, withholding of antibiotics in all children with AOM, regardless of clinical course, would risk a return to the suppurative complications observed in the

preantibiotic era. At the population level, antibiotics halve the risk of mastoiditis after AOM, but the high NNT of approximately 4800 patients to prevent 1 case of mastoiditis precludes a strategy of universal antibiotic therapy as a means to prevent mastoiditis.⁸³

The favorable natural history of AOM makes it difficult to demonstrate significant differences in efficacy between antibiotic and placebo when a successful outcome is defined by relief or improvement of presenting signs and symptoms. In contrast, when otoscopic improvement (resolution of TM bulging, intense erythema, or both) is also required for a positive outcome,^{31,32} the NNT is 3 to 4, compared with 8 to 16 for symptom improvement alone in older studies that used less precise diagnostic criteria. MEE, however, may persist for weeks or months after an AOM episode and is not a criterion for otoscopic failure.

National guidelines for initial observation of AOM in select children were first implemented in the Netherlands⁹⁷ and subsequently in Sweden,⁹⁸ Scotland,⁹⁹ the United States,¹ the United Kingdom,¹⁰⁰ and Italy.¹⁰¹ All included observation as an initial treatment option under specified circumstances. In numerous studies, only approximately one-third of children initially observed received a rescue antibiotic for persistent or worsening AOM,^{30,32,76,81,89,102} suggesting that antibiotic use could potentially be reduced by 65% in eligible children. Given the high incidence of AOM, this reduction could help substantially in curtailing antibiotic-related adverse events.

McCormick et al³⁰ reported on 233 patients randomly assigned to receive immediate antibiotics (amoxicillin, 90 mg/kg/day) or to undergo watchful waiting. Criteria for inclusion were symptoms of ear infection, otoscopic evidence of AOM, and nonsevere AOM

based on a 3-item symptom score (OM-3) and TM appearance based on an 8-item scale (OS-8). Primary outcomes were parent satisfaction with AOM care, resolution of AOM symptoms after initial treatment, AOM failure and recurrence, and nasopharyngeal carriage of *S pneumoniae* strains resistant to antibiotics after treatment. The study was confounded by including patients who had received antibiotics in the previous 30 days.

In the watchful waiting group, 66% of children completed the study without antibiotics. There was no difference in parent satisfaction scores at day 12. A 5-item symptom score (ETG-5) was assessed at days 0 to 10 by using patient diaries. Subjects receiving immediate antibiotics resolved their symptoms faster than did subjects who underwent watchful waiting ($P = .004$). For children younger than 2 years, the difference was greater ($P = .008$). Otoscopic and tympanogram scores were also lower in the antibiotic group as opposed to the watchful waiting group ($P = .02$ for otoscopic score, $P = .004$ for tympanogram). Combining all ages, failure and recurrence rates were lower for the antibiotic group (5%) than for the watchful waiting group (21%) at 12 days. By day 30, there was no difference in failure or recurrence for the antibiotic and watchful waiting groups (23% and 24%, respectively). The association between clinical outcome and intervention group was not significantly different between age groups. Immediate antibiotics resulted in eradication of *S pneumoniae* carriage in the majority of children, but *S pneumoniae* strains cultured from children in the antibiotic group at day 12 were more likely to be multidrug resistant than were strains cultured from children in the watchful waiting group.

The decision not to give initial antibiotic treatment and observe should be

a joint decision of the clinician and the parents. In such cases, a system for close follow-up and a means of beginning antibiotics must be in place if symptoms worsen or no improvement is seen in 48 to 72 hours.

Initial observation of AOM should be part of a larger management strategy that includes analgesics, parent information, and provisions for a rescue antibiotic. Education of parents should include an explanation about the self-limited nature of most episodes of AOM, especially in children 2 years and older; the importance of pain management early in the course; and the potential adverse effects of antibiotics. Such an approach can substantially reduce prescription fill rates for rescue antibiotics.¹⁰³

A critical component of any strategy involving initial observation for AOM is the ability to provide a rescue antibiotic if needed. This is often done by using a "safety net" or a "wait-and-see prescription,"^{76,102} in which the parent/caregiver is given an antibiotic prescription during the clinical encounter but is instructed to fill the prescription only if the child fails to improve within 2 to 3 days or if symptoms worsen at any time. An alternative approach is not to provide a written prescription but to instruct the parent/caregiver to call or return if the child fails to improve within 2 to 3 days or if symptoms worsen.

In one of the first major studies of observation with a safety-net antibiotic prescription (SNAP), Siegel et al¹⁰² enrolled 194 patients with protocol defined AOM, of whom 175 completed the study. Eligible patients were given a SNAP with instructions to fill the prescription only if symptoms worsened or did not improve in 48 hours. The SNAP was valid for 5 days. Pain medicine was recommended to be taken as needed. A phone interview was conducted 5 to 10 days after diagnosis.

One hundred twenty of 175 families did not fill the prescription. Reasons for filling the prescription (more than 1 reason per patient was acceptable) were as follows: continued pain, 23%; continued fever, 11%; sleep disruption, 6%; missed days of work, 3%; missed days of child care, 3%; and no reason given, 5%. One 16-month-old boy completed observation successfully but 6 weeks later developed AOM in the opposite ear, was treated with antibiotics, and developed postauricular cellulitis.

In a similar study of a “wait-and-see prescription” (WASP) in the emergency department, Spiro et al⁷⁶ randomly assigned 283 patients to either a WASP or standard prescription. Clinicians were educated on the 2004 AAP diagnostic criteria and initial treatment options for AOM; however, diagnosis was made at the discretion of the clinician. Patients were excluded if they did not qualify for observation per the 2004 guidelines. The primary outcome was whether the prescription was filled within 3 days of diagnosis. Prescriptions were not filled for 62% and 13% of the WASP and standard prescription patients, respectively ($P < .001$). Reasons for filling the prescription in the WASP group were fever (60%), ear pain (34%), or fussy behavior (6%). No serious adverse events were reported.

Strategies to observe children with AOM who are likely to improve on their own without initial antibiotic therapy reduces common adverse effects of antibiotics, such as diarrhea and diaper dermatitis. In 2 trials, antibiotic therapy significantly increased the absolute rates of diarrhea by 10% to 20% and of diaper rash or dermatitis by 6% to 16%.^{31,32} Reduced antibiotic use may also reduce the prevalence of resistant bacterial pathogens. Multidrug-resistant *S pneumoniae* continues to be a significant concern for AOM, despite universal immunization of

children in the United States with heptavalent pneumococcal conjugate vaccine.^{104,105} In contrast, countries with low antibiotic use for AOM have a low prevalence of resistant nasopharyngeal pathogens in children.¹⁰⁶

Key Action Statement 4A

Clinicians should prescribe amoxicillin for AOM when a decision

to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4A

Aggregate evidence quality	Grade B
Benefits	Effective antibiotic for most children with AOM. Inexpensive, safe, acceptable taste, narrow antimicrobial spectrum.
Risks, harms, cost	Ineffective against β -lactamase-producing organisms. Adverse effects of amoxicillin.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Better to use a drug that has reasonable cost, has an acceptable taste, and has a narrow antibacterial spectrum.
Intentional vagueness	The clinician must determine whether the patient is truly penicillin allergic.
Role of patient preferences	Should be considered if previous bad experience with amoxicillin.
Exclusions	Patients with known penicillin allergy.
Strength	Recommendation.

Key Action Statement 4B

Clinicians should prescribe an antibiotic with additional β -lactamase coverage for AOM when a decision to treat with antibiotics has been made *and* the child has received

amoxicillin in the past 30 days *or* has concurrent purulent conjunctivitis *or* has a history of recurrent AOM unresponsive to amoxicillin. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4B

Aggregate evidence quality	Grade C
Benefits	Successful treatment of β -lactamase-producing organisms.
Risks, harms, cost	Cost of antibiotic. Increased adverse effects.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Efficacy is more important than taste.
Intentional vagueness	None.
Role of patient preferences	Concern regarding side effects and taste.
Exclusions	Patients with known penicillin allergy.
Strength	Recommendation

Key Action Statement 4C

Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the

initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4C

Aggregate evidence quality	Grade B
Benefits	Identify children who may have AOM caused by pathogens resistant to previous antibiotics.
Risks, harms, cost	Cost. Time for patient and clinician to make change. Potential need for parenteral medication.
Benefit-harm assessment	Preponderance of benefit.
Value judgments	None.
Intentional vagueness	"Reassess" is not defined. The clinician may determine the method of assessment.
Role of patient preferences	Limited.
Exclusions	Appearance of TM improved.
Strength	Recommendation

Purpose of This Section

If an antibiotic will be used for treatment of a child with AOM, whether as initial management or after a period of observation, the clinician must choose an antibiotic that will have a high likelihood of being effective against the most likely etiologic bacterial pathogens with considerations of cost, taste, convenience, and adverse effects. This section proposes first- and second-line antibiotics that best meet these criteria while balancing potential benefits and harms.

Changes From AAP/AAFP 2004 AOM Guideline

Despite new data on the effect of PCV7 and updated data on the in vitro susceptibility of bacterial pathogens most likely to cause AOM, the recommendations for the first-line antibiotic remains unchanged from 2004. The current guideline contains revised recommendations regarding penicillin allergy based on new data. The increase of multidrug-resistant strains of pneumococci is noted.

Microbiology

Microorganisms detected in the middle ear during AOM include pathogenic bacteria, as well as respiratory viruses.^{107–110} AOM occurs most frequently as a consequence of viral upper respiratory tract infection,^{111–113} which leads to eustachian tube inflammation/

dysfunction, negative middle ear pressure, and movement of secretions containing the upper respiratory tract infection causative virus and pathogenic bacteria in the nasopharynx into the middle ear cleft. By using comprehensive and sensitive microbiologic testing, bacteria and/or viruses can be detected in the middle ear fluid in up to 96% of AOM cases (eg, 66% bacteria and viruses together, 27% bacteria alone, and 4% virus alone).¹¹⁴ Studies using less sensitive or less comprehensive microbiologic assays have yielded less positive results for bacteria and much less positive results for viruses.^{115–117} The 3 most common bacterial pathogens in AOM are *S pneumoniae*, nontypeable *Haemophilus influenzae*, and *Moraxella catarrhalis*.¹¹¹ *Streptococcus pyogenes* (group A β -hemolytic streptococci) accounts for less than 5% of AOM cases. The proportion of AOM cases with pathogenic bacteria isolated from the middle ear fluids varies depending on bacteriologic techniques, transport issues, and stringency of AOM definition. In series of reports from the United States and Europe from 1952–1981 and 1985–1992, the mean percentage of cases with bacterial pathogens isolated from the middle ear fluids was 69% and 72%, respectively.¹¹⁸ A large series from the University of Pittsburgh Otitis Media Study Group reported bacterial pathogens in 84% of the middle ear fluids

from 2807 cases of AOM.¹¹⁸ Studies that applied more stringent otoscopic criteria and/or use of bedside specimen plating on solid agar in addition to liquid transport media have a reported rate of recovery of pathogenic bacteria from middle ear exudates ranging from 85% to 90%.^{119–121} When using appropriate stringent diagnostic criteria, careful specimen handling, and sensitive microbiologic techniques, the vast majority of cases of AOM will involve pathogenic bacteria either alone or in concert with viral pathogens.

Among AOM bacterial pathogens, *S pneumoniae* was the most frequently cultured in earlier reports. Since the debut and routine use of PCV7 in 2000, the ordinal frequency of these 3 major middle ear pathogens has evolved.¹⁰⁵ In the first few years after PCV7 introduction, *H influenzae* became the most frequently isolated middle ear pathogen, replacing *S pneumoniae*.^{122,123} Shortly thereafter, a shift to non-PCV7 serotypes of *S pneumoniae* was described.¹²⁴ Pichichero et al¹⁰⁴ later reported that 44% of 212 AOM cases seen in 2003–2006 were caused by *H influenzae*, and 28% were caused by *S pneumoniae*, with a high proportion of highly resistant *S pneumoniae*. In that study, a majority (77%) of cases involved recurrent disease or initial treatment failure. A later report¹²⁵ with data from 2007 to 2009, 6 to 8 years after the introduction of PCV7 in the United States, showed that PCV7 strains of *S pneumoniae* virtually disappeared from the middle ear fluid of children with AOM who had been vaccinated. However, the frequency of isolation of non-PCV7 serotypes of *S pneumoniae* from the middle ear fluid overall was increased; this has made isolation of *S pneumoniae* and *H influenzae* of children with AOM nearly equal.

In a study of tympanocentesis over 4 respiratory tract illness seasons in a private practice, the percentage of

S pneumoniae initially decreased relative to *H influenzae*. In 2005–2006 ($N = 33$), 48% of bacteria were *S pneumoniae*, and 42% were *H influenzae*. For 2006–2007 ($N = 37$), the percentages were equal at 41%. In 2007–2008 ($N = 34$), 35% were *S pneumoniae*, and 59% were *H influenzae*. In 2008–2009 ($N = 24$), the percentages were 54% and 38%, respectively, with an increase in intermediate and non-susceptible *S pneumoniae*.¹²⁶ Data on nasopharyngeal colonization from PCV7-immunized children with AOM have shown continued presence of *S pneumoniae* colonization. Revai et al¹²⁷ showed no difference in *S pneumoniae* colonization rate among children with AOM who have been unimmunized, underimmunized, or fully immunized with PCV7. In a study during a viral upper respiratory tract infection, including mostly PCV7-immunized children (6 months to 3 years of age), *S pneumoniae* was detected in 45.5% of 968 nasopharyngeal swabs, *H influenzae* was detected in 32.4%, and *M catarrhalis* was detected in 63.1%.¹²⁸ Data show that nasopharyngeal colonization of children vaccinated with PCV7 increasingly is caused by *S pneumoniae* serotypes not contained in the vaccine.^{129–132} With the use of the recently licensed 13-valent pneumococcal conjugate vaccine (PCV13),¹³³ the patterns of nasopharyngeal colonization and infection with these common AOM bacterial pathogens will continue to evolve.

Investigators have attempted to predict the type of AOM pathogenic bacteria on the basis of clinical severity, but results have not been promising. *S pyogenes* has been shown to occur more commonly in older children¹³⁴ and to cause a greater degree of inflammation of the middle ear and TM, a greater frequency of spontaneous rupture of the TM, and more frequent progression to acute mastoiditis

compared with other bacterial pathogens.^{134–136} As for clinical findings in cases with *S pneumoniae* and nontypeable *H influenzae*, some studies suggest that signs and symptoms of AOM caused by *S pneumoniae* may be more severe (fever, severe earache, bulging TM) than those caused by other pathogens.^{44,121,137} These findings were refuted by results of the studies that found AOM caused by nontypeable *H influenzae* to be associated with bilateral AOM and more severe inflammation of the TM.^{96,138} Leibovitz et al¹³⁹ concluded, in a study of 372 children with AOM caused by *H influenzae* ($N = 138$), *S pneumoniae* ($N = 64$), and mixed *H influenzae* and *S pneumoniae* ($N = 64$), that clinical/otologic scores could not discriminate among various bacterial etiologies of AOM. However, there were significantly different clinical/otologic scores between bacterial culture negative and culture positive cases. A study of middle ear exudates of 82 cases of bullous myringitis has shown a 97% bacteria positive rate, primarily *S pneumoniae*. In contrast to the previous belief, mycoplasma is rarely the causative agent in this condition.¹⁴⁰ Accurate prediction of the bacterial cause of AOM on the basis of clinical presentation, without bacterial culture of the middle ear exudates, is not possible, but specific etiologies may be predicted in some situations. Published evidence has suggested that AOM associated with conjunctivitis (otitis-conjunctivitis syndrome) is more likely caused by nontypeable *H influenzae* than by other bacteria.^{141–143}

Bacterial Susceptibility to Antibiotics

Selection of antibiotic to treat AOM is based on the suspected type of bacteria and antibiotic susceptibility pattern, although clinical pharmacology

and clinical and microbiologic results and predicted compliance with the drug are also taken into account. Early studies of AOM patients show that 19% of children with *S pneumoniae* and 48% with *H influenzae* cultured on initial tympanocentesis who were not treated with antibiotic cleared the bacteria at the time of a second tympanocentesis 2 to 7 days later.¹⁴⁴ Approximately 75% of children infected with *M catarrhalis* experienced bacteriologic cure even after treatment with amoxicillin, an antibiotic to which it is not susceptible.^{145,146}

Antibiotic susceptibility of major AOM bacterial pathogens continues to change, but data on middle ear pathogens have become scanty because tympanocentesis is not generally performed in studies of children with uncomplicated AOM. Most available data come from cases of persistent or recurrent AOM. Current US data from a number of centers indicates that approximately 83% and 87% of isolates of *S pneumoniae* from all age groups are susceptible to regular (40 mg/kg/day) and high-dose amoxicillin (80–90 mg/kg/day divided twice daily), respectively.^{130,147–150} Pediatric isolates are smaller in number and include mostly ear isolates collected from recurrent and persistent AOM cases with a high percentage of multidrug-resistant *S pneumoniae*, most frequently nonvaccine serotypes that have recently increased in frequency and importance.¹⁰⁴

High-dose amoxicillin will yield middle ear fluid levels that exceed the minimum inhibitory concentration (MIC) of all *S pneumoniae* serotypes that are intermediately resistant to penicillin (penicillin MICs, 0.12–1.0 µg/mL), and many but not all highly resistant serotypes (penicillin MICs, ≥ 2 µg/mL) for a longer period of the dosing interval and has been shown to improve bacteriologic and clinical efficacy

compared with the regular dose.^{151–153} Hoberman et al¹⁵⁴ reported superior efficacy of high-dose amoxicillin-clavulanate in eradication of *S pneumoniae* (96%) from the middle ear at days 4 to 6 of therapy compared with azithromycin.

The antibiotic susceptibility pattern for *S pneumoniae* is expected to continue to evolve with the use of PCV13, a conjugate vaccine containing 13 serotypes of *S pneumoniae*.^{133,155,156} Widespread use of PCV13 could potentially reduce diseases caused by multidrug-resistant pneumococcal serotypes and diminish the need for the use of higher dose of amoxicillin or amoxicillin-clavulanate for AOM.

Some *H influenzae* isolates produce β -lactamase enzyme, causing the isolate to become resistant to penicillins. Current data from different studies with non-AOM sources and geographic locations that may not be comparable show that 58% to 82% of *H influenzae* isolates are susceptible to regular- and high-dose amoxicillin.^{130,147,148,157,158} These data represented a significant decrease in β -lactamase-producing *H*

influenzae, compared with data reported in the 2004 AOM guideline.

Nationwide data suggest that 100% of *M catarrhalis* derived from the upper respiratory tract are β -lactamase-positive but remain susceptible to amoxicillin-clavulanate.¹⁵⁹ However, the high rate of spontaneous clinical resolution occurring in children with AOM attributable to *M catarrhalis* treated with amoxicillin reduces the concern for the first-line coverage for this microorganism.^{145,146} AOM attributable to *M catarrhalis* rarely progresses to acute mastoiditis or intracranial infections.^{102,160,161}

Antibiotic Therapy

High-dose amoxicillin is recommended as the first-line treatment in most patients, although there are a number of medications that are clinically effective (Table 5). The justification for the use of amoxicillin relates to its effectiveness against common AOM bacterial pathogens as well as its safety, low cost, acceptable taste, and narrow microbiologic spectrum.^{145,151} In children who have taken amoxicillin in the previous 30 days, those with concurrent conjunctivitis, or those

for whom coverage for β -lactamase-positive *H influenzae* and *M catarrhalis* is desired, therapy should be initiated with high-dose amoxicillin-clavulanate (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day of clavulanate, a ratio of amoxicillin to clavulanate of 14:1, given in 2 divided doses, which is less likely to cause diarrhea than other amoxicillin-clavulanate preparations).¹⁶²

Alternative initial antibiotics include cefdinir (14 mg/kg per day in 1 or 2 doses), cefuroxime (30 mg/kg per day in 2 divided doses), cefpodoxime (10 mg/kg per day in 2 divided doses), or ceftriaxone (50 mg/kg, administered intramuscularly). It is important to note that alternative antibiotics vary in their efficacy against AOM pathogens. For example, recent US data on in vitro susceptibility of *S pneumoniae* to cefdinir and cefuroxime are 70% to 80%, compared with 84% to 92% amoxicillin efficacy.^{130,147–149} In vitro efficacy of cefdinir and cefuroxime against *H influenzae* is approximately 98%, compared with 58% efficacy of amoxicillin and nearly 100% efficacy of amoxicillin-clavulanate.¹⁵⁸ A multicenter double tympanocentesis open-label study of

TABLE 5 Recommended Antibiotics for (Initial or Delayed) Treatment and for Patients Who Have Failed Initial Antibiotic Treatment

Initial Immediate or Delayed Antibiotic Treatment		Antibiotic Treatment After 48–72 h of Failure of Initial Antibiotic Treatment	
Recommended First-line Treatment	Alternative Treatment (if Penicillin Allergy)	Recommended First-line Treatment	Alternative Treatment
Amoxicillin (80–90 mg/kg per day in 2 divided doses)	Cefdinir (14 mg/kg per day in 1 or 2 doses)	Amoxicillin-clavulanate ^a (90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate in 2 divided doses)	Ceftriaxone, 3 d Clindamycin (30–40 mg/kg per day in 3 divided doses), with or without third-generation cephalosporin
or	Cefuroxime (30 mg/kg per day in 2 divided doses)	or	Failure of second antibiotic
Amoxicillin-clavulanate ^a (90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate [amoxicillin to clavulanate ratio, 14:1] in 2 divided doses)	Cefpodoxime (10 mg/kg per day in 2 divided doses)	Ceftriaxone (50 mg IM or IV for 3 d)	Clindamycin (30–40 mg/kg per day in 3 divided doses) plus third-generation cephalosporin
	Ceftriaxone (50 mg IM or IV per day for 1 or 3 d)		Tympanocentesis ^b Consult specialist ^b

IM, intramuscular; IV, intravenous.

^a May be considered in patients who have received amoxicillin in the previous 30 d or who have the otitis-conjunctivitis syndrome.

^b Perform tympanocentesis/drainage if skilled in the procedure, or seek a consultation from an otolaryngologist for tympanocentesis/drainage. If the tympanocentesis reveals multidrug-resistant bacteria, seek an infectious disease specialist consultation.

^c Cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are highly unlikely to be associated with cross-reactivity with penicillin allergy on the basis of their distinct chemical structures. See text for more information.

cefdinir in recurrent AOM attributable to *H influenzae* showed eradication of the organism in 72% of patients.¹⁶³

For penicillin-allergic children, recent data suggest that cross-reactivity among penicillins and cephalosporins is lower than historically reported.^{164–167} The previously cited rate of cross-sensitivity to cephalosporins among penicillin-allergic patients (approximately 10%) is likely an overestimate. The rate was based on data collected and reviewed during the 1960s and 1970s. A study analyzing pooled data of 23 studies, including 2400 patients with reported history of penicillin allergy and 39 000 with no penicillin allergic history concluded that many patients who present with a history of penicillin allergy do not have an immunologic reaction to penicillin.¹⁶⁶ The chemical structure of the cephalosporin determines the risk of cross-reactivity between specific agents.^{165,168} The degree of cross-reactivity is higher between penicillins and first-generation cephalosporins but is negligible with the second- and third-generation cephalosporins. Because of the differences in the chemical structures, cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are highly unlikely to be associated with cross-reactivity with penicillin.¹⁶⁵ Despite this, the Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; and Joint Council of Allergy, Asthma and Immunology¹⁶⁹ stated that “cephalosporin treatment of patients with a history of penicillin allergy, selecting out those with severe reaction histories, show a reaction rate of 0.1%.” They recommend a cephalosporin in cases without severe and/or recent penicillin allergy reaction history when skin test is not available.

Macrolides, such as erythromycin and azithromycin, have limited efficacy against both *H influenzae* and *S pneumoniae*.^{130,147–149} Clindamycin lacks efficacy against *H influenzae*. Clindamycin alone (30–40 mg/kg per day in 3 divided doses) may be used for suspected penicillin-resistant *S pneumoniae*; however, the drug will likely not be effective for the multidrug-resistant serotypes.^{130,158,166}

Several of these choices of antibiotic suspensions are barely palatable or frankly offensive and may lead to avoidance behaviors or active rejection by spitting out the suspension. Palatability of antibiotic suspensions has been compared in many studies.^{170–172} Specific antibiotic suspensions such as cefuroxime, cefpodoxime, and clindamycin may benefit from adding taste-masking products, such as chocolate or strawberry flavoring agents, to obscure the initial bitter taste and the unpleasant aftertaste.^{172,173} In the patient who is persistently vomiting or cannot otherwise tolerate oral medication, even when the taste is masked, ceftriaxone (50 mg/kg, administered intramuscularly in 1 or 2 sites in the anterior thigh, or intravenously) has been demonstrated to be effective for the initial or repeat antibiotic treatment of AOM.^{174,175} Although a single injection of ceftriaxone is approved by the US FDA for the treatment of AOM, results of a double tympanocentesis study (before and 3 days after single dose ceftriaxone) by Leibovitz et al¹⁷⁵ suggest that more than 1 ceftriaxone dose may be required to prevent recurrence of the middle ear infection within 5 to 7 days after the initial dose.

Initial Antibiotic Treatment Failure

When antibiotics are prescribed for AOM, clinical improvement should be noted within 48 to 72 hours. During the 24 hours after the diagnosis of AOM,

the child's symptoms may worsen slightly. In the next 24 hours, the patient's symptoms should begin to improve. If initially febrile, the temperature should decline within 48 to 72 hours. Irritability and fussiness should lessen or disappear, and sleeping and drinking patterns should normalize.^{176,177} If the patient is not improved by 48 to 72 hours, another disease or concomitant viral infection may be present, or the causative bacteria may be resistant to the chosen therapy.

Some children with AOM and persistent symptoms after 48 to 72 hours of initial antibacterial treatment may have combined bacterial and viral infection, which would explain the persistence of ongoing symptoms despite appropriate antibiotic therapy.^{109,178,179} Literature is conflicting on the correlation between clinical and bacteriologic outcomes. Some studies report good correlation ranging from 86% to 91%,^{180,181} suggesting continued presence of bacteria in the middle ear in a high proportion of cases with persistent symptoms. Others report that middle ear fluid from children with AOM in whom symptoms are persistent is sterile in 42% to 49% of cases.^{123,182} A change in antibiotic may not be required in some children with mild persistent symptoms.

In children with persistent, severe symptoms of AOM and unimproved otologic findings after initial treatment, the clinician may consider changing the antibiotic (Table 5). If the child was initially treated with amoxicillin and failed to improve, amoxicillin-clavulanate should be used. Patients who were given amoxicillin-clavulanate or oral third-generation cephalosporins may receive intramuscular ceftriaxone (50 mg/kg). In the treatment of AOM unresponsive to initial antibiotics, a 3-day course of ceftriaxone has been shown to be better than a 1-day regimen.¹⁷⁵

Although trimethoprim-sulfamethoxazole and erythromycin-sulfisoxazole had been useful as therapy for patients with AOM, pneumococcal surveillance studies have indicated that resistance to these 2 combination agents is substantial.^{130,149,183} Therefore, when patients fail to improve while receiving amoxicillin, neither trimethoprim-sulfamethoxazole¹⁸⁴ nor erythromycin-sulfisoxazole is appropriate therapy.

Tympanocentesis should be considered, and culture of middle ear fluid should be performed for bacteriologic diagnosis and susceptibility testing when a series of antibiotic drugs have failed to improve the clinical condition. If tympanocentesis is not available, a course of clindamycin may be used, with or without an antibiotic that covers nontypeable *H influenzae* and *M catarrhalis*, such as cefdinir, cefixime, or cefuroxime.

Because *S pneumoniae* serotype 19A is usually multidrug-resistant and may not be responsive to clindamycin,^{104,149} newer antibiotics that are not approved by the FDA for treatment of AOM, such as levofloxacin or linezolid, may be indicated.^{185–187} Levofloxacin is a quinolone antibiotic that is not approved by the FDA for use in children. Linezolid is effective against resistant Gram-positive bacteria. It is not approved by the FDA for AOM treatment and is expensive. In children with repeated treatment failures, every effort should be made for bacteriologic diagnosis by tympanocentesis with Gram stain, culture, and antibiotic susceptibility testing of the organism(s) present. The clinician may consider consulting with pediatric medical subspecialists, such as an otolaryngologist for possible tympanocentesis, drainage, and culture and an infectious disease expert, before use of unconventional drugs such as levofloxacin or linezolid.

When tympanocentesis is not available, 1 possible way to obtain information on the middle ear pathogens and their antimicrobial susceptibility is to obtain a nasopharyngeal specimen for bacterial culture. Almost all middle ear pathogens derive from the pathogens colonizing the nasopharynx, but not all nasopharyngeal pathogens enter the middle ear to cause AOM. The positive predictive value of nasopharyngeal culture during AOM (likelihood that bacteria cultured from the nasopharynx is the middle ear pathogen) ranges from 22% to 44% for *S pneumoniae*, 50% to 71% for nontypeable *H influenzae*, and 17% to 19% for *M catarrhalis*. The negative predictive value (likelihood that bacteria not found in the nasopharynx are not AOM pathogens) ranges from 95% to 99% for all 3 bacteria.^{188,189} Therefore, if nasopharyngeal culture is negative for specific bacteria, that organism is likely not the AOM pathogen. A negative culture for *S pneumoniae*, for example, will help eliminate the concern for multidrug-resistant bacteria and the need for unconventional therapies, such as levofloxacin or linezolid. On the other hand, if *S pneumoniae* is cultured from the nasopharynx, the antimicrobial susceptibility pattern can help guide treatment.

Duration of Therapy

The optimal duration of therapy for patients with AOM is uncertain; the usual 10-day course of therapy was derived from the duration of treatment of streptococcal pharyngotonsillitis. Several studies favor standard 10-day therapy over shorter courses for children younger than 2 years.^{162,190–194} Thus, for children younger than 2 years and children with severe symptoms, a standard 10-day course is recommended. A 7-day course of oral antibiotic appears to be equally effective in children 2 to 5 years of age with mild or moderate AOM. For children 6 years and older with mild to moderate

symptoms, a 5- to 7-day course is adequate treatment.

Follow-up of the Patient With AOM

Once the child has shown clinical improvement, follow-up is based on the usual clinical course of AOM. There is little scientific evidence for a routine 10- to 14-day reevaluation visit for all children with an episode of AOM. The physician may choose to reassess some children, such as young children with severe symptoms or recurrent AOM or when specifically requested by the child's parent.

Persistent MEE is common and can be detected by pneumatic otoscopy (with or without verification by tympanometry) after resolution of acute symptoms. Two weeks after successful antibiotic treatment of AOM, 60% to 70% of children have MEE, decreasing to 40% at 1 month and 10% to 25% at 3 months after successful antibiotic treatment.^{177,195} The presence of MEE without clinical symptoms is defined as OME. OME must be differentiated clinically from AOM and requires infrequent additional monitoring but not antibiotic therapy. Assurance that OME resolves is particularly important for parents of children with cognitive or developmental delays that may be affected adversely by transient hearing loss associated with MEE. Detailed recommendations for the management of the child with OME can be found in the evidence-based guideline from the AAP/AAFP/American Academy of Otolaryngology-Head and Neck Surgery published in 2004.^{84,85}

Key Action Statement 5A

Clinicians should *NOT* prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 5A

Aggregate evidence quality	Grade B
Benefits	No adverse effects from antibiotic. Reduces potential for development of bacterial resistance. Reduced costs.
Risks, harms, cost	Small increase in episodes of AOM.
Benefit-harm assessment	Preponderance of benefit.
Value judgments	Potential harm outweighs the potential benefit.
Intentional vagueness	None.
Role of patient preferences	Limited.
Exclusions	Young children whose only alternative would be tympanostomy tubes.
Strength	Recommendation

Key Action Statement 5B

Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in

1 year, with 1 episode in the preceding 6 months). (Evidence Quality: Grade B, Rec. Strength: Option)

Key Action Statement Profile: KAS 5B

Aggregate evidence quality	Grade B
Benefits	Decreased frequency of AOM. Ability to treat AOM with topical antibiotic therapy.
Risks, harms, cost	Risks of anesthesia or surgery. Cost. Scarring of TM, chronic perforation, cholesteatoma. Otorrhea.
Benefits-harms assessment	Equilibrium of benefit and harm.
Value judgments	None.
Intentional vagueness	Option based on limited evidence.
Role of patient preferences	Joint decision of parent and clinician.
Exclusions	Any contraindication to anesthesia and surgery.
Strength	Option

Purpose of This Section

Recurrent AOM has been defined as the occurrence of 3 or more episodes of AOM in a 6-month period or the occurrence of 4 or more episodes of AOM in a 12-month period that includes at least 1 episode in the preceding 6 months.²⁰ These episodes should be well documented and separate acute infections.¹¹

Winter season, male gender, and passive exposure to smoking have been associated with an increased likelihood of recurrence. Half of children younger than 2 years treated for AOM will experience a recurrence within 6 months. Symptoms that last more than 10 days may also predict recurrence.¹⁹⁶

Changes From AAP/AAFP 2004 AOM Guideline

Recurrent AOM was not addressed in the 2004 AOM guideline. This section

addresses the literature on recurrent AOM.

Antibiotic Prophylaxis

Long-term, low-dose antibiotic use, referred to as antibiotic prophylaxis or chemoprophylaxis, has been used to treat children with recurrent AOM to prevent subsequent episodes.⁸⁵ A 2006 Cochrane review analyzed 16 studies of long-term antibiotic use for AOM and found such use prevented 1.5 episodes of AOM per year, reducing in half the number of AOM episodes during the period of treatment.¹⁹⁷ Randomized placebo-controlled trials of prophylaxis reported a decrease of 0.09 episodes per month in the frequency of AOM attributable to therapy (approximately 0.5 to 1.5 AOM episodes per year for 95% of children). An estimated 5 children would need to be treated for 1

year to prevent 1 episode of OM. The effect may be more substantial for children with 6 or more AOM episodes in the preceding year.¹²

This decrease in episodes of AOM occurred only while the prophylactic antibiotic was being given. The modest benefit afforded by a 6-month course of antibiotic prophylaxis does not have longer-lasting benefit after cessation of therapy. Teele showed no differences between children who received prophylactic antibiotics compared with those who received placebo in AOM recurrences or persistence of OME.¹⁹⁸

Antibiotic prophylaxis is not appropriate for children with long-term MEE or for children with infrequent episodes of AOM. The small reduction in frequency of AOM with long-term antibiotic prophylaxis must be weighed against the cost of such therapy; the potential adverse effects of antibiotics, principally allergic reaction and gastrointestinal tract consequences, such as diarrhea; and their contribution to the emergence of bacterial resistance.

Surgery for Recurrent AOM

The use of tympanostomy tubes for treatment of ear disease in general, and for AOM in particular, has been controversial.¹⁹⁹ Most published studies of surgical intervention for OM focus on children with persistent MEE with or without AOM. The literature on surgery for recurrent AOM as defined here is scant. A lack of consensus among otolaryngologists regarding the role of surgery for recurrent AOM was reported in a survey of Canadian otolaryngologists in which 40% reported they would “never,” 30% reported they would “sometimes,” and 30% reported they would “often or always” place tympanostomy tubes for a hypothetical 2-year-old child with frequent OM without persistent MEE or hearing loss.²⁰⁰

Tympanostomy tubes, however, remain widely used in clinical practice for both OME and recurrent OM.²⁰¹ Recurrent

AOM remains a common indication for referral to an otolaryngologist.

Three randomized controlled trials have compared the number of episodes of AOM after tympanostomy tube placement or no surgery.²⁰² Two found significant improvement in mean number of AOM episodes after tympanostomy tubes during a 6-month follow-up period.^{203,204} One study randomly assigned children with recurrent AOM to groups receiving placebo, amoxicillin prophylaxis, or tympanostomy tubes and followed them for 2 years.²⁰⁵ Although prophylactic antibiotics reduced the rate of AOM, no difference in number of episodes of AOM was noted between the tympanostomy tube group and the placebo group over 2 years. A Cochrane review of studies of tympanostomy tubes for recurrent AOM analyzed 2 studies^{204,206} that met inclusion criteria and found that tympanostomy tubes reduced the number of episodes of AOM by 1.5 episodes in the 6 months after surgery.²⁰⁷ Tympanostomy tube insertion has been shown to improve disease-specific quality-of-life measures in children with OM.²⁰⁸ One multicenter, nonrandomized observational study showed large improvements in a disease-specific quality-of-life instrument that measured psychosocial domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns that are associated with ear infections.²⁰⁹ These benefits of tympanostomy tubes have been demonstrated in mixed populations of children that include children with OME as well as recurrent AOM.

Beyond the cost, insertion of tympanostomy tubes is associated with a small but finite surgical and anesthetic risk. A recent review looking at protocols to minimize operative risk reported no major complications, such as sensorineural hearing loss, vascular injury,

or ossicular chain disruption, in 10 000 tube insertions performed primarily by residents, although minor complications such as TM tears or displaced tubes in the middle ear were seen in 0.016% of ears.²¹⁰ Long-term sequelae of tympanostomy tubes include TM structural changes including focal atrophy, tympanosclerosis, retraction pockets, and chronic perforation. One meta-analysis found tympanosclerosis in 32% of patients after placement of tympanostomy tubes and chronic perforations in 2.2% of patients who had short-term tubes and 16.6% of patients with long-term tubes.²¹¹

Adenoidectomy, without myringotomy and/or tympanostomy tubes, did not reduce the number of episodes of AOM

when compared with chemoprophylaxis or placebo.²¹² Adenoidectomy alone should not be used for prevention of AOM but may have benefit when performed with placement of tympanostomy tubes or in children with previous tympanostomy tube placement in OME.²¹³

Prevention of AOM: Key Action Statement 6A

Pneumococcal Vaccine

Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 6A

Aggregate evidence quality		Grade B
Benefits	Reduced frequency of AOM attributable to vaccine serotypes. Reduced risk of serious pneumococcal systemic disease.	
Risks, harms, cost	Potential vaccine side effects. Cost of vaccine.	
Benefits-harms assessment	Preponderance of benefit.	
Value judgments	Potential vaccine adverse effects are minimal.	
Intentional vagueness	None.	
Role of patient preferences	Some parents may choose to refuse the vaccine.	
Exclusions	Severe allergic reaction (eg, anaphylaxis) to any component of pneumococcal vaccine or any diphtheria toxoid-containing vaccine.	
Strength	Strong Recommendation	

Key Action Statement 6B

Influenza Vaccine: Clinicians should recommend annual influenza vaccine to all children according to the schedule of

the Advisory Committee on Immunization Practices, AAP, and AAFP. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6B

Aggregate evidence quality		Grade B
Benefits	Reduced risk of influenza infection. Reduction in frequency of AOM associated with influenza.	
Risks, harms, cost	Potential vaccine adverse effects. Cost of vaccine. Requires annual immunization.	
Benefits-harms assessment	Preponderance of benefit.	
Value judgments	Potential vaccine adverse effects are minimal.	
Intentional vagueness	None	
Role of patient preferences	Some parents may choose to refuse the vaccine.	
Exclusions	See CDC guideline on contraindications (http://www.cdc.gov/flu/professionals/acip/shouldnot.htm).	
Strength	Recommendation	

Key Action Statement 6C

Breastfeeding: Clinicians should encourage exclusive breastfeeding

for at least 6 months. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6C

Aggregate evidence quality		Grade B
Benefits	May reduce the risk of early AOM. Multiple benefits of breastfeeding unrelated to AOM.	
Risk, harm, cost	None	
Benefit-harm assessment	Preponderance of benefit.	
Value judgments	The intervention has value unrelated to AOM prevention.	
Intentional vagueness	None	
Role of patient preferences	Some parents choose to feed formula.	
Exclusions	None	
Strength	Recommendation	

Key Action Statement 6D

Clinicians should encourage avoidance of tobacco smoke ex-

posure. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6D

Aggregate evidence quality		Grade C
Benefits	May reduce the risk of AOM.	
Risks, harms, cost	None	
Benefits-harms assessment	Preponderance of benefit.	
Value judgments	Avoidance of tobacco exposure has inherent value unrelated to AOM.	
Intentional vagueness	None	
Role of patient preferences	Many parents/caregivers choose not to stop smoking. Some also remain addicted, and are unable to quit smoking.	
Exclusions	None	
Strength	Recommendation	

Purpose of This Section

The 2004 AOM guideline noted data on immunizations, breastfeeding, and lifestyle changes that would reduce the risk of acquiring AOM. This section addresses new data published since 2004.

Changes From AAP/AAFP 2004 AOM Guideline

PCV7 has been in use in the United States since 2000. PCV13 was introduced in the United States in 2010. The 10-valent pneumococcal nontypeable *H influenzae* protein D-conjugate vaccine was recently licensed in Europe for

prevention of diseases attributable to *S pneumoniae* and nontypeable *H influenzae*. Annual influenza immunization is now recommended for all children 6 months of age and older in the United States.^{214,215} Updated information regarding these vaccines and their effect on the incidence of AOM is reviewed.

The AAP issued a new breastfeeding policy statement in February 2012.²¹⁶ This guideline also includes a recommendation regarding tobacco smoke exposure. Bottle propping, pacifier use, and child care are discussed, but no recommendations are made because of limited evidence. The use of

xylitol, a possible adjunct to AOM prevention, is discussed; however, no recommendations are made.

Pneumococcal Vaccine

Pneumococcal conjugate vaccines have proven effective in preventing OM caused by pneumococcal serotypes contained in the vaccines. A meta-analysis of 5 studies with AOM as an outcome determined that there is a 29% reduction in AOM caused by all pneumococcal serotypes among children who received PCV7 before 24 months of age.²¹⁷ Although the overall benefit seen in clinical trials for all causes of AOM is small (6%–7%),^{218–221} observational studies have shown that medical office visits for otitis were reduced by up to 40% comparing years before and after introduction of PCV7.^{222–224} Grijvala²²³ reported no effect, however, among children first vaccinated at older ages. Poehling et al²²⁵ reported reductions of frequent AOM and PE tube use after introduction of PCV7. The observations by some of greater benefit observed in the community than in clinical trials is not fully understood but may be related to effects of herd immunity or may be attributed to secular trends or changes in AOM diagnosis patterns over time.^{223,226–229} In a 2009 Cochrane review,²²¹ Jansen et al found that the overall reduction in AOM incidence may only be 6% to 7% but noted that even that small rate may have public health relevance. O'Brien et al concurred and noted in addition the potential for cost savings.²³⁰ There is evidence that serotype replacement may reduce the long-term efficacy of pneumococcal conjugate vaccines against AOM,²³¹ but it is possible that new pneumococcal conjugate vaccines may demonstrate an increased effect on reduction in AOM.^{232–234} Data on AOM reduction secondary to the PCV13 licensed in the United States in 2010 are not yet available.

The *H influenzae* protein D-conjugate vaccine recently licensed in Europe has potential benefit of protection against 10 serotypes of *S pneumoniae* and nontypeable *H influenzae*.^{221,234}

Influenza Vaccine

Most cases of AOM follow upper respiratory tract infections caused by viruses, including influenza viruses. As many as two-thirds of young children with influenza may have AOM.²³⁵ Investigators have studied the efficacy of trivalent inactivated influenza vaccine (TIV) and live-attenuated intranasal influenza vaccine (LAIV) in preventing AOM. Many studies have demonstrated 30% to 55% efficacy of influenza vaccine in prevention of AOM during the respiratory illness season.^{6,235–239} One study reported no benefit of TIV in reducing AOM burden; however, 1 of the 2 respiratory illness seasons during which this study was conducted had a relatively low influenza activity. A pooled analysis²⁴⁰ of 8 studies comparing LAIV versus TIV or placebo^{241–248} showed a higher efficacy of LAIV compared with both placebo and with TIV. Influenza vaccination is now recommended for all children 6 months of age and older in the United States.^{214,215}

Breastfeeding

Multiple studies provide evidence that breastfeeding for at least 4 to 6 months reduces episodes of AOM and recurrent AOM.^{249–253} Two cohort studies, 1 retrospective study²⁵⁰ and 1 prospective study,²⁵³ suggest a dose response, with some protection from partial breastfeeding and the greatest protection from exclusive breastfeeding through 6 months of age. In multivariate analysis controlling for exposure to child care settings, the risk of nonrecurrent otitis is 0.61 (95% confidence interval [CI]: 0.4–0.92) comparing exclusive breastfeeding

through 6 months of age with no breastfeeding or breastfeeding less than 4 months. In a prospective cohort, Scariatti²⁵³ found a significant dose-response effect. In this study, OM was self-reported by parents. In a systematic review, McNiel et al²⁵⁴ found that when exclusive breastfeeding was set as the normative standard, the recalculated odds ratios (ORs) revealed the risks of any formula use. For example, any formula use in the first 6 months of age was significantly associated with increased incidence of OM (OR: 1.78; 95% CI: 1.19–2.70; OR: 4.55; 95% CI: 1.64–12.50 in the available studies; pooled OR for any formula in the first 3 months of age, 2.00; 95% CI: 1.40–2.78). A number of studies^{255–259} addressed the association of AOM and other infectious illness in infants with duration and exclusivity of breastfeeding, but all had limitations and none had a randomized controlled design. However, taken together, they continue to show a protective effect of exclusive breastfeeding. In all studies, there has been a predominance of white subjects, and child care attendance and smoking exposure may not have been completely controlled. Also, feeding methods were self-reported.

The consistent finding of a lower incidence of AOM and recurrent AOM with increased breastfeeding supports the AAP recommendation to encourage exclusive breastfeeding for the first 6 months of life and to continue for at least the first year and beyond for as long as mutually desired by mother and child.²¹⁶

Lifestyle Changes

In addition to its many other benefits,²⁶⁰ eliminating exposure to passive tobacco smoke has been postulated to reduce the incidence of AOM in infancy.^{252,261–264} Bottles and pacifiers have been associated with AOM.

Avoiding supine bottle feeding (“bottle propping”) and reducing or eliminating pacifier use in the second 6 months of life may reduce AOM incidence.^{265–267} In a recent cohort study, pacifier use was associated with AOM recurrence.²⁶⁸

During infancy and early childhood, reducing the incidence of upper respiratory tract infections by altering child care-center attendance patterns can reduce the incidence of recurrent AOM significantly.^{249,269}

Xylitol

Xylitol, or birch sugar, is chemically a pentitol or 5-carbon polyol sugar alcohol. It is available as chewing gum, syrup, or lozenges. A 2011 Cochrane review²⁷⁰ examined the evidence for the use of xylitol in preventing recurrent AOM. A statistically significant 25% reduction in the risk of occurrence of AOM among healthy children at child care centers in the xylitol group compared with the control group (relative risk: 0.75; 95% CI: 0.65 to 0.88; RD: –0.07; 95% CI: –0.12 to –0.03) in the 4 studies met criteria for analysis.^{271–274} Chewing gum and lozenges containing xylitol appeared to be more effective than syrup. Children younger than 2 years, those at the greatest risk of having AOM, cannot safely use lozenges or chewing gum. Also, xylitol needs to be given 3 to 5 times a day to be effective. It is not effective for treating AOM and it must be taken daily throughout the respiratory illness season to have an effect. Sporadic or as-needed use is not effective.

Future Research

Despite advances in research partially stimulated by the 2004 AOM guideline, there are still many unanswered clinical questions in the field. Following are possible clinical research questions that still need to be resolved.

Diagnosis

There will probably never be a gold standard for diagnosis of AOM because of the continuum from OME to AOM. Conceivably, new techniques that could be used on the small amount of fluid obtained during tympanocentesis could identify inflammatory markers in addition to the presence of bacteria or viruses. However, performing tympanocentesis studies on children with uncomplicated otitis is likely not feasible because of ethical and other considerations.

Devices that more accurately identify the presence of MEE and bulging that are easier to use than tympanometry during office visits would be welcome, especially in the difficult-to-examine infant. Additional development of inexpensive, easy-to-use video pneumatic otoscopes is still a goal.

Initial Treatment

The recent studies of Hoberman³¹ and Tähtinen³² have addressed clinical and TM appearance by using stringent diagnostic criteria of AOM. However, the outcomes for less stringent diagnostic criteria, a combination of symptoms, MEE, and TM appearance not completely consistent with OME can only be inferred from earlier studies that used less stringent criteria but did not specify outcomes for various grades of findings. Randomized controlled trials on these less certain TM appearances using scales similar to the OS-8 scale³⁵ could clarify the benefit of initial antibiotics and initial observation for these less certain diagnoses. Such studies must also specify severity of illness, laterality, and otorrhea.

Appropriate end points must be established. Specifically is the appearance of the TM in patients without clinical symptoms at the end of a study significant for relapse, recurrence, or

persistent MEE. Such a study would require randomization of patients with unimproved TM appearance to continued observation and antibiotic groups.

The most efficient and acceptable methods of initial observation should continue to be studied balancing the convenience and benefits with the potential risks to the patient.

Antibiotics

Amoxicillin-clavulanate has a broader spectrum than amoxicillin and may be a better initial antibiotic. However, because of cost and adverse effects, the subcommittee has chosen amoxicillin as first-line AOM treatment. Randomized controlled trials comparing the 2 with adequate power to differentiate clinical efficacy would clarify this choice. Stringent diagnostic criteria should be the standard for these studies. Antibiotic comparisons for AOM should now include an observation arm for patients with non-severe illness to ensure a clinical benefit over placebo. Studies should also have enough patients to show small but meaningful differences.

Although there have been studies on the likelihood of resistant *S pneumoniae* or *H influenzae* in children in child care settings and with siblings younger than 5 years, studies are still needed to determine whether these and other risk factors would indicate a need for different initial treatment than noted in the guideline.

New antibiotics that are safe and effective are needed for use in AOM because of the development of multidrug-resistant organisms. Such new antibiotics must be tested against the currently available medications.

Randomized controlled trials using different durations of antibiotic therapy in different age groups are needed to optimize therapy with the possibility

of decreasing duration of antibiotic use. These would need to be performed initially with amoxicillin and amoxicillin-clavulanate but should also be performed for any antibiotic used in AOM. Again, an observation arm should be included in nonsevere illness.

Recurrent AOM

There have been adequate studies regarding prophylactic antibiotic use in recurrent AOM. More and better controlled studies of tympanostomy tube placement would help determine its benefit versus harm.

Prevention

There should be additional development of vaccines targeted at common organisms associated with AOM.²⁷⁵ Focused epidemiologic studies on the benefit of breastfeeding, specifically addressing AOM prevention, including duration of breastfeeding and partial versus exclusive breastfeeding, would clarify what is now a more general database. Likewise, more focused studies of the effects of lifestyle changes would help clarify their effect on AOM.

Complementary and Alternative Medicine

There are no well-designed randomized controlled trials of the usefulness of complementary and alternative medicine in AOM, yet a large number of families turn to these methods. Although most alternative therapies are relatively inexpensive, some may be costly. Such studies should compare the alternative therapy to observation rather than antibiotics and only use an antibiotic arm if the alternative therapy is shown to be better than observation. Such studies should focus on children with less stringent criteria of AOM but using the same descriptive criteria for the patients as noted above.

DISSEMINATION OF GUIDELINES

An Institute of Medicine Report notes that “Effective multifaceted implementation strategies targeting both individuals and healthcare systems should be employed by implementers to promote adherence to trustworthy [clinical practice guidelines].”²³⁰

Many studies of the effect of clinical practice guidelines have been performed. In general, the studies show little overt change in practice after a guideline is published. However, as was seen after the 2004 AOM guideline, the number of visits for AOM and the number of prescriptions for antibiotics for AOM had decreased publication. Studies of educational and dissemination methods both at the practicing physician level and especially at the resident level need to be examined.

SUBCOMMITTEE ON DIAGNOSIS AND MANAGEMENT OF ACUTE OTITIS MEDIA

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Otitis Media With Effusion

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- *Clinical Practice Guideline*

AMERICAN ACADEMY OF PEDIATRICS

CLINICAL PRACTICE GUIDELINE

American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, and American Academy of Pediatrics Subcommittee on Otitis Media With Effusion

Otitis Media With Effusion

ABSTRACT. The clinical practice guideline on otitis media with effusion (OME) provides evidence-based recommendations on diagnosing and managing OME in children. This is an update of the 1994 clinical practice guideline "Otitis Media With Effusion in Young Children," which was developed by the Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality). In contrast to the earlier guideline, which was limited to children 1 to 3 years old with no craniofacial or neurologic abnormalities or sensory deficits, the updated guideline applies to children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The American Academy of Pediatrics, American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery selected a subcommittee composed of experts in the fields of primary care, otolaryngology, infectious diseases, epidemiology, hearing, speech and language, and advanced-practice nursing to revise the OME guideline.

The subcommittee made a strong recommendation that clinicians use pneumatic otoscopy as the primary diagnostic method and distinguish OME from acute otitis media.

The subcommittee made recommendations that clinicians should 1) document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME, 2) distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and more promptly evaluate hearing, speech, language, and need for intervention in children at risk, and 3) manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown).

The subcommittee also made recommendations that 4) hearing testing be conducted when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME, 5) children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected, and 6) when a child becomes a surgical candidate (tympanostomy tube insertion is the preferred initial procedure). Adenoidectomy should not be performed unless a distinct indication exists (nasal ob-

struction, chronic adenoiditis); repeat surgery consists of adenoidectomy plus myringotomy with or without tubeinsertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME.

The subcommittee made negative recommendations that 1) population-based screening programs for OME not be performed in healthy, asymptomatic children, and 2) because antihistamines and decongestants are ineffective for OME, they should not be used for treatment; antimicrobials and corticosteroids do not have long-term efficacy and should not be used for routine management.

The subcommittee gave as options that 1) tympanometry can be used to confirm the diagnosis of OME and 2) when children with OME are referred by the primary clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of acute otitis media and developmental status of the child. The subcommittee made no recommendations for 1) complementary and alternative medicine as a treatment for OME, based on a lack of scientific evidence documenting efficacy, or 2) allergy management as a treatment for OME, based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME. Last, the panel compiled a list of research needs based on limitations of the evidence reviewed.

The purpose of this guideline is to inform clinicians of evidence-based methods to identify, monitor, and manage OME in children aged 2 months through 12 years. The guideline may not apply to children more than 12 years old, because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change. The target population includes children with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The guideline is intended for use by providers of health care to children, including primary care and specialist physicians, nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child-development specialists. The guideline is applicable to any setting in which children with OME would be identified, monitored, or managed.

This guideline is not intended as a sole source of guidance in evaluating children with OME. Rather, it is designed to assist primary care and other clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all children with this condition and may not provide the only appropriate approach to diagnosing and managing this problem. *Pediatrics* 2004;113:1412-1429; *acute otitis media, antibacterial, antibiotic.*

ABBREVIATIONS. OME, otitis media with effusion; AOM, acute otitis media; AAP, American Academy of Pediatrics; AHRQ, Agency for Healthcare Research and Quality; EPC, Southern California Evidence-Based Practice Center; CAM, complementary and alternative medicine; HL, hearing level.

Otitis media with effusion (OME) as discussed in this guideline is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection.^{1,2} OME is considered distinct from acute otitis media (AOM), which is defined as a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. Persistent middle-ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction.³ Approximately 2.2 million diagnosed episodes of OME occur annually in the United States, yielding a combined direct and indirect annual cost estimate of \$4.0 billion.²

OME may occur spontaneously because of poor eustachian tube function or as an inflammatory response following AOM. Approximately 90% of children (80% of individual ears) have OME at some time before school age,⁴ most often between ages 6 months and 4 years.⁵ In the first year of life, >50% of children will experience OME, increasing to >60% by 2 years.⁶ Many episodes resolve spontaneously within 3 months, but ~30% to 40% of children have recurrent OME, and 5% to 10% of episodes last 1 year or longer.^{1,4,7}

The primary outcomes considered in the guideline include hearing loss; effects on speech, language, and learning; physiologic sequelae; health care utilization (medical, surgical); and quality of life.^{1,2} The high prevalence of OME, difficulties in diagnosis and assessing duration, increased risk of conductive hearing loss, potential impact on language and cognition, and significant practice variations in management⁸ make OME an important condition for the use of up-to-date evidence-based practice guidelines.

METHODS

General Methods and Literature Search

In developing an evidence-based clinical practice guideline on managing OME, the American Academy of Pediatrics (AAP), American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery worked with the Agency for Healthcare Research and Quality (AHRQ) and other organizations. This effort included representatives from each partnering organization along with liaisons from audiology, speech-language pathology, informatics, and advanced-practice nursing. The most current literature on managing children with OME was reviewed, and research questions were developed to guide the evidence-review process.

The AHRQ report on OME from the Southern California Evidence-Based Practice Center (EPC) focused on key questions of natural history, diagnostic methods, and long-term speech, language, and hearing outcomes.² Searches were conducted through January 2000 in Medline, Embase, and the Cochrane Library. Additional articles were identified by review of reference listings in proceedings, reports, and other guidelines. The EPC accepted 970 articles for full review after screening 3200 abstracts. The EPC reviewed articles by using established quality criteria^{9,10} and included randomized trials, prospective cohorts, and validations of diagnostic tests (validating cohort studies).

The AAP subcommittee on OME updated the AHRQ review with articles identified by an electronic Medline search through April 2003 and with additional material identified manually by subcommittee members. Copies of relevant articles were distributed to the subcommittee for consideration. A specific search for articles relevant to complementary and alternative medicine (CAM) was performed by using Medline and the Allied and Complementary Medicine Database through April 2003. Articles relevant to allergy and OME were identified by using Medline through April 2003. The subcommittee met 3 times over a 1-year period, ending in May 2003, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.¹¹

In May 2003, the Guidelines Review Group of the Yale Center for Medical Informatics used the Guideline Elements Model¹² to categorize content of the present draft guideline. Policy statements were parsed into component decision variables and actions and then assessed for decidability and executability. Quality appraisal using established criteria¹³ was performed with Guideline Elements Model-Q Online.^{14,15} Implementation issues were predicted by using the Implementability Rating Profile, an instrument under development by the Yale Guidelines Review Group (R. Shiffman, MD, written communication, May 2003). OME subcommittee members received summary results and modified an advanced draft of the guideline.

The final draft practice guideline underwent extensive peer review by numerous entities identified by the subcommittee. Comments were compiled and reviewed by the subcommittee cochairpersons. The recommendations contained in the practice guideline are based on the best available published data through April 2003. Where data are lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, produce optimal health outcomes for patients, and minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The AAP definitions for evidence-based statements¹⁶ are listed in Tables 1 and 2.

Guidelines are never intended to overrule professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability.¹⁷ All clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.¹⁶

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Value judgments applied by the OME subcommittee were made in an effort to minimize harm and diminish unnecessary therapy. Emphasis was placed on promptly identifying and managing children at risk for speech, language, or learning problems to maximize opportunities for beneficial outcomes. Direct costs also were considered in the statements concerning diagnosis and screening and to a lesser extent in other statements.

1A. PNEUMATIC OTOSCOPY: CLINICIANS SHOULD USE PNEUMATIC OTOSCOPY AS THE PRIMARY DIAGNOSTIC METHOD FOR OME, AND OME SHOULD BE DISTINGUISHED FROM AOM

This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm.

TABLE 1. Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). [*] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). [*] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) [*] or that well-done studies (grade A, B, or C) [*] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means that there is both a lack of pertinent evidence (grade D) [*] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

^{*} See Table 2 for the definitions of evidence grades.

TABLE 2. Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case-control and cohort design)
D	Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

1B. TYMPANOMETRY: TYMPANOMETRY CAN BE USED TO CONFIRM THE DIAGNOSIS OF OME

This option is based on cohort studies and a balance of benefit and harm.

Diagnosing OME correctly is fundamental to proper management. Moreover, OME must be differentiated from AOM to avoid unnecessary antimicrobial use.^{18,19}

OME is defined as fluid in the middle ear without signs or symptoms of acute ear infection.² The tympanic membrane is often cloudy with distinctly impaired mobility,²⁰ and an air-fluid level or bubble may be visible in the middle ear. Conversely, diagnosing AOM requires a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. The critical distinguishing feature is that

only AOM has acute signs and symptoms. Distinct redness of the tympanic membrane should not be a criterion for prescribing antibiotics, because it has poor predictive value for AOM and is present in ~5% of ears with OME.²⁰

The AHRQ evidence report² systematically reviewed the sensitivity, specificity, and predictive values of 9 diagnostic methods for OME. Pneumatic otoscopy had the best balance of sensitivity and specificity, consistent with the 1994 guideline.¹ Meta-analysis revealed a pooled sensitivity of 94% (95% confidence interval: 91%–96%) and specificity of 80% (95% confidence interval: 75%–86%) for validated observers using pneumatic otoscopy versus myringotomy as the gold standard. Pneumatic otoscopy therefore should remain the primary method of OME diagnosis, because the instrument is readily available

in practice settings, cost-effective, and accurate in experienced hands. Non-pneumatic otoscopy is not advised for primary diagnosis.

The accuracy of pneumatic otoscopy in routine clinical practice may be less than that shown in published results, because clinicians have varying training and experience.^{21,22} When the diagnosis of OME is uncertain, tympanometry or acoustic reflectometry should be considered as an adjunct to pneumatic otoscopy. Tympanometry with a standard 226-Hz probe tone is reliable for infants 4 months old or older and has good interobserver agreement of curve patterns in routine clinical practice.^{23,24} Younger infants require specialized equipment with a higher probe tone frequency. Tympanometry generates costs related to instrument purchase, annual calibration, and test administration. Acoustic reflectometry with spectral gradient analysis is a low-cost alternative to tympanometry that does not require an airtight seal in the ear canal; however, validation studies primarily have used children 2 years old or older with a high prevalence of OME.^{25–27}

Although no research studies have examined whether pneumatic otoscopy causes discomfort, expert consensus suggests that the procedure does not have to be painful, especially when symptoms of acute infection (AOM) are absent. A nontraumatic examination is facilitated by using a gentle touch, restraining the child properly when necessary, and inserting the speculum only into the outer one third (cartilaginous portion) of the ear canal.²⁸ The pneumatic bulb should be compressed slightly before insertion, because OME often is associated with a negative middle-ear pressure, which can be assessed more accurately by releasing the already compressed bulb. The otoscope must be fully charged, the bulb (halogen or xenon) bright and luminescent,²⁹ and the insufflator bulb attached tightly to the head to avoid the loss of an air seal. The window must also be sealed.

Evidence Profile: Pneumatic Otoscopy

- Aggregate evidence quality: A, diagnostic studies in relevant populations.
- Benefit: improved diagnostic accuracy; inexpensive equipment.
- Harm: cost of training clinicians in pneumatic otoscopy.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: strong recommendation.

Evidence Profile: Tympanometry

- Aggregate evidence quality: B, diagnostic studies with minor limitations.
- Benefit: increased diagnostic accuracy beyond pneumatic otoscopy; documentation.
- Harm: acquisition cost, administrative burden, and recalibration.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: option.

1C. SCREENING: POPULATION-BASED SCREENING PROGRAMS FOR OME ARE NOT RECOMMENDED IN HEALTHY, ASYMPTOMATIC CHILDREN

This recommendation is based on randomized, controlled trials and cohort studies, with a preponderance of harm over benefit.

This recommendation concerns population-based screening programs of all children in a community or a school without regard to any preexisting symptoms or history of disease. This recommendation does not address hearing screening or monitoring of specific children with previous or recurrent OME.

OME is highly prevalent in young children. Screening surveys of healthy children ranging in age from infancy to 5 years old show a 15% to 40% point prevalence of middle-ear effusion.^{5,7,30–36} Among children examined at regular intervals for a year, ~50% to 60% of child care center attendees³² and 25% of school-aged children³⁷ were found to have a middle-ear effusion at some time during the examination period, with peak incidence during the winter months.

Population-based screening has not been found to influence short-term language outcomes,³³ and its long-term effects have not been evaluated in a randomized, clinical trial. Therefore, the recommendation against screening is based not only on the ability to identify OME but more importantly on a lack of demonstrable benefits from treating children so identified that exceed the favorable natural history of the disease. The New Zealand Health Technology Assessment³⁸ could not determine whether preschool screening for OME was effective. More recently, the Canadian Task Force on Preventive Health Care³⁹ reported that insufficient evidence was available to recommend including or excluding routine early screening for OME. Although screening for OME is not inherently harmful, potential risks include inaccurate diagnoses, overtreating self-limited disease, parental anxiety, and the costs of screening and unnecessary treatment.

Population-based screening is appropriate for conditions that are common, can be detected by a sensitive and specific test, and benefit from early detection and treatment.⁴⁰ The first 2 requirements are fulfilled by OME, which affects up to 80% of children by school entry^{2,5,7} and can be screened easily with tympanometry (see recommendation 1B). Early detection and treatment of OME identified by screening, however, have not been shown to improve intelligence, receptive language, or expressive language.^{2,39,41,42} Therefore, population-based screening for early detection of OME in asymptomatic children has not been shown to improve outcomes and is not recommended.

Evidence Profile: Screening

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations and consistent evidence from observational studies.
- Benefit: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence.

- Harm: inaccurate diagnosis (false-positive or false-negative), overtreating self-limited disease, parental anxiety, cost of screening, and/or unnecessary treatment.
- Benefits-harms assessment: preponderance of harm over benefit.
- Policy level: recommendation against.

2. DOCUMENTATION: CLINICIANS SHOULD DOCUMENT THE LATERALITY, DURATION OF EFFUSION, AND PRESENCE AND SEVERITY OF ASSOCIATED SYMPTOMS AT EACH ASSESSMENT OF THE CHILD WITH OME

This recommendation is based on observational studies and strong preponderance of benefit over harm.

Documentation in the medical record facilitates diagnosis and treatment and communicates pertinent information to other clinicians to ensure patient safety and reduce medical errors.⁴³ Management decisions in children with OME depend on effusion duration and laterality plus the nature and severity of associated symptoms. Therefore, these features should be documented at every medical encounter for OME. Although no studies have addressed documentation for OME specifically, there is room for improvement in documentation of ambulatory care medical records.⁴⁴

Ideally, the time of onset and laterality of OME can be defined through diagnosis of an antecedent AOM, a history of acute onset of signs or symptoms directly referable to fluid in the middle ear, or the presence of an abnormal audiogram or tympanogram closely after a previously normal test. Unfortunately, these conditions are often lacking, and the clinician is forced to speculate on the onset and duration of fluid in the middle ear(s) in a child found to have OME at a routine office visit or school screening audiometry.

In ~40% to 50% of cases of OME, neither the affected children nor their parents or caregivers describe significant complaints referable to a middle-ear effusion.^{45,46} In some children, however, OME may have associated signs and symptoms caused by inflammation or the presence of effusion (not acute infection) that should be documented, such as

- Mild intermittent ear pain, fullness, or “popping”
- Secondary manifestations of ear pain in infants, which may include ear rubbing, excessive irritability, and sleep disturbances
- Failure of infants to respond appropriately to voices or environmental sounds, such as not turning accurately toward the sound source
- Hearing loss, even when not specifically described by the child, suggested by seeming lack of attentiveness, behavioral changes, failure to respond to normal conversational-level speech, or the need for excessively high sound levels when using audio equipment or viewing television
- Recurrent episodes of AOM with persistent OME between episodes
- Problems with school performance
- Balance problems, unexplained clumsiness, or delayed gross motor development^{47–50}
- Delayed speech or language development

The laterality (unilateral versus bilateral), duration of effusion, and presence and severity of associated symptoms should be documented in the medical record at each assessment of the child with OME. When OME duration is uncertain, the clinician must take whatever evidence is at hand and make a reasonable estimate.

Evidence Profile: Documentation

- Aggregate evidence quality: C, observational studies.
- Benefits: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and, if consistently unilateral, may identify a problem with specific ear other than OME (eg, retraction pocket or cholesteatoma).
- Harm: administrative burden.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

3. CHILD AT RISK: CLINICIANS SHOULD DISTINGUISH THE CHILD WITH OME WHO IS AT RISK FOR SPEECH, LANGUAGE, OR LEARNING PROBLEMS FROM OTHER CHILDREN WITH OME AND SHOULD EVALUATE HEARING, SPEECH, LANGUAGE, AND NEED FOR INTERVENTION MORE PROMPTLY

This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.

The panel defines the child at risk as one who is at increased risk for developmental difficulties (delay or disorder) because of sensory, physical, cognitive, or behavioral factors listed in Table 3. These factors are not caused by OME but can make the child less tolerant of hearing loss or vestibular problems secondary to middle-ear effusion. In contrast the child with OME who is not at risk is otherwise healthy and does not have any of the factors shown in Table 3.

Earlier guidelines for managing OME have applied only to young children who are healthy and exhibit no developmental delays.¹ Studies of the relationship between OME and hearing loss or speech/language development typically exclude children with craniofacial anomalies, genetic syndromes, and other developmental disorders. Therefore, the available literature mainly applies to otherwise healthy children who meet inclusion criteria for randomized,

TABLE 3. Risk Factors for Developmental Difficulties*

Permanent hearing loss independent of OME
Suspected or diagnosed speech and language delay or disorder
Autism-spectrum disorder and other pervasive developmental disorders
Syndromes (eg, Down) or craniofacial disorders that include cognitive, speech, and language delays
Blindness or uncorrectable visual impairment
Cleft palate with or without associated syndrome
Developmental delay

* Sensory, physical, cognitive, or behavioral factors that place children who have OME at an increased risk for developmental difficulties (delay or disorder).

controlled trials. Few, if any, existing studies dealing with developmental sequelae caused by hearing loss from OME can be generalized to children who are at risk.

Children who are at risk for speech or language delay would likely be affected additionally by hearing problems from OME,⁵¹ although definitive studies are lacking. For example, small comparative studies of children or adolescents with Down syndrome⁵² or cerebral palsy⁵³ show poorer articulation and receptive language associated with a history of early otitis media. Large studies are unlikely to be forthcoming because of methodologic and ethical difficulties inherent in studying children who are delayed or at risk for further delays. Therefore, clinicians who manage children with OME should determine whether other conditions coexist that put a child at risk for developmental delay (Table 3) and then take these conditions into consideration when planning assessment and management.

Children with craniofacial anomalies (eg, cleft palate; Down syndrome; Robin sequence; coloboma, heart defect, choanal atresia, retarded growth and development, genital anomaly, and ear defect with deafness [CHARGE] association) have a higher prevalence of chronic OME, hearing loss (conductive and sensorineural), and speech or language delay than do children without these anomalies.^{54–57} Other children may not be more prone to OME but are likely to have speech and language disorders, such as those children with permanent hearing loss independent of OME,^{58,59} specific language impairment,⁶⁰ autism-spectrum disorders,⁶¹ or syndromes that adversely affect cognitive and linguistic development. Some retrospective studies^{52,62,63} have found that hearing loss caused by OME in children with cognitive delays, such as Down syndrome, has been associated with lower language levels. Children with language delays or disorders with OME histories perform more poorly on speech-perception tasks than do children with OME histories alone.^{64,65}

Children with severe visual impairments may be more susceptible to the effects of OME, because they depend on hearing more than children with normal vision.⁵¹ Any decrease in their most important remaining sensory input for language (hearing) may significantly compromise language development and their ability to interact and communicate with others. All children with severe visual impairments should be considered more vulnerable to OME sequelae, especially in the areas of balance, sound localization, and communication.

Management of the child with OME who is at increased risk for developmental delays should include hearing testing and speech and language evaluation and may include speech and language therapy concurrent with managing OME, hearing aids or other amplification devices for hearing loss independent of OME, tympanostomy tube insertion,^{54,63,66,67} and hearing testing after OME resolves to document improvement, because OME can mask a permanent underlying hearing loss and delay detection.^{59,68,69}

Evidence Profile: Child at Risk

- Aggregate evidence quality: C, observational studies of children at risk; D, expert opinion on the ability of prompt assessment and management to alter outcomes.
- Benefits: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational interventions because of hearing problems from OME.
- Harm: cost, time, and specific risks of medications or surgery.
- Benefits-harms assessment: exceptional preponderance of benefits over harm based on subcommittee consensus because of circumstances to date precluding randomized trials.
- Policy level: recommendation.

4. WATCHFUL WAITING: CLINICIANS SHOULD MANAGE THE CHILD WITH OME WHO IS NOT AT RISK WITH WATCHFUL WAITING FOR 3 MONTHS FROM THE DATE OF EFFUSION ONSET (IF KNOWN) OR DIAGNOSIS (IF ONSET IS UNKNOWN)

This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.

This recommendation is based on the self-limited nature of most OME, which has been well documented in cohort studies and in control groups of randomized trials.^{2,70}

The likelihood of spontaneous resolution of OME is determined by the cause and duration of effusion.⁷⁰ For example, ~75% to 90% of residual OME after an AOM episode resolves spontaneously by 3 months.^{71–73} Similar outcomes of defined onset during a period of surveillance in a cohort study are observed for OME.^{32,37} Another favorable situation involves improvement (not resolution) of newly detected OME defined as change in tympanogram from type B (flat curve) to non-B (anything other than a flat curve). Approximately 55% of children so defined improve by 3 months,⁷⁰ but one third will have OME relapse within the next 3 months.⁴ Although a type B tympanogram is an imperfect measure of OME (81% sensitivity and 74% specificity versus myringotomy), it is the most widely reported measure suitable for deriving pooled resolution rates.^{2,70}

Approximately 25% of newly detected OME of unknown prior duration in children 2 to 4 years old resolves by 3 months when resolution is defined as a change in tympanogram from type B to type A/C1 (peak pressure >200 daPa).^{2,70,74–77} Resolution rates may be higher for infants and young children in whom the preexisting duration of effusion is generally shorter, and particularly for those observed prospectively in studies or in the course of well-child care. Documented bilateral OME of 3 months' duration or longer resolves spontaneously after 6 to 12 months in ~30% of children primarily 2 years old or older, with only marginal benefits if observed longer.⁷⁰

Any intervention for OME (medical or surgical) other than observation carries some inherent harm. There is little harm associated with a specified period of observation in the child who is not at risk for speech, language, or learning problems. When observing children with OME, clinicians should inform the parent or caregiver that the child may experience reduced hearing until the effusion resolves, especially if it is bilateral. Clinicians may discuss strategies for optimizing the listening and learning environment until the effusion resolves. These strategies include speaking in close proximity to the child, facing the child and speaking clearly, repeating phrases when misunderstood, and providing preferential classroom seating.^{78,79}

The recommendation for a 3-month period of observation is based on a clear preponderance of benefit over harm and is consistent with the original OME guideline intent of avoiding unnecessary surgery.¹ At the discretion of the clinician, this 3-month period of watchful waiting may include interval visits at which OME is monitored by using pneumatic otoscopy, tympanometry, or both. Factors to consider in determining the optimal interval(s) for follow-up include clinical judgment, parental comfort level, unique characteristics of the child and/or his environment, access to a health care system, and hearing levels (HLs) if known.

After documented resolution of OME in all affected ears, additional follow-up is unnecessary.

Evidence Profile: Watchful Waiting

- Aggregate evidence quality: B, systematic review of cohort studies.
- Benefit: avoid unnecessary interventions, take advantage of favorable natural history, and avoid unnecessary referrals and evaluations.
- Harm: delays in therapy for OME that will not resolve with observation; prolongation of hearing loss.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

5. MEDICATION: ANTIHISTAMINES AND DECONGESTANTS ARE INEFFECTIVE FOR OME AND ARE NOT RECOMMENDED FOR TREATMENT; ANTIMICROBIALS AND CORTICOSTEROIDS DO NOT HAVE LONG-TERM EFFICACY AND ARE NOT RECOMMENDED FOR ROUTINE MANAGEMENT

This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.

Therapy for OME is appropriate only if persistent and clinically significant benefits can be achieved beyond spontaneous resolution. Although statistically significant benefits have been demonstrated for some medications, they are short-term and relatively small in magnitude. Moreover, significant adverse events may occur with all medical therapies.

The prior OME guideline¹ found no data supporting antihistamine-decongestant combinations in treating OME. Meta-analysis of 4 randomized trials showed no significant benefit for antihistamines or decongestants versus placebo. No additional studies have been published since 1994 to change this recommendation. Adverse effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability.

Long-term benefits of antimicrobial therapy for OME are unproved despite a modest short-term benefit for 2 to 8 weeks in randomized trials.^{1,80,81} Initial benefits, however, can become nonsignificant within 2 weeks of stopping the medication.⁸² Moreover, ~7 children would need to be treated with antimicrobials to achieve one short-term response.¹ Adverse effects of antimicrobials are significant and may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, development of bacterial resistance,⁸³ and cost. Societal consequences include direct transmission of resistant bacterial pathogens in homes and child care centers.⁸⁴

The prior OME guideline¹ did not recommend oral steroids for treating OME in children. A later meta-analysis⁸⁵ showed no benefit for oral steroid versus placebo within 2 weeks but did show a short-term benefit for oral steroid plus antimicrobial versus antimicrobial alone in 1 of 3 children treated. This benefit became nonsignificant after several weeks in a prior meta-analysis¹ and in a large, randomized trial.⁸⁶ Oral steroids can produce behavioral changes, increased appetite, and weight gain.¹ Additional adverse effects may include adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head.³ Although intranasal steroids have fewer adverse effects, one randomized trial⁸⁷ showed statistically equivalent outcomes at 12 weeks for intranasal beclomethasone plus antimicrobials versus antimicrobials alone for OME.

Antimicrobial therapy with or without steroids has not been demonstrated to be effective in long-term resolution of OME, but in some cases this therapy can be considered an option because of short-term benefit in randomized trials, when the parent or caregiver expresses a strong aversion to impending surgery. In this circumstance, a single course of therapy for 10 to 14 days may be used. The likelihood that the OME will resolve long-term with these regimens is small, and prolonged or repetitive courses of antimicrobials or steroids are strongly not recommended.

Other nonsurgical therapies that are discussed in the OME literature include autoinflation of the eustachian tube, oral or intratympanic use of mucolytics, and systemic use of pharmacologic agents other than antimicrobials, steroids, and antihistamine-decongestants. Insufficient data exist for any of these therapies to be recommended in treating OME.³

Evidence Profile: Medication

- Aggregate evidence quality: A, systematic review of well-designed, randomized, controlled trials.

- Benefit: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse.
- Harm: adverse effects of specific medications as listed previously; societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens.
- Benefits-harms assessment: preponderance of harm over benefit.
- Policy level: recommendation against.

6. HEARING AND LANGUAGE: HEARING TESTING IS RECOMMENDED WHEN OME PERSISTS FOR 3 MONTHS OR LONGER OR AT ANY TIME THAT LANGUAGE DELAY, LEARNING PROBLEMS, OR A SIGNIFICANT HEARING LOSS IS SUSPECTED IN A CHILD WITH OME; LANGUAGE TESTING SHOULD BE CONDUCTED FOR CHILDREN WITH HEARING LOSS

This recommendation is based on cohort studies and the preponderance of benefit over risk.

Hearing Testing

Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected. Conductive hearing loss often accompanies OME^{1,88} and may adversely affect binaural processing,⁸⁹ sound localization,⁹⁰ and speech perception in noise.^{91–94} Hearing loss caused by OME may impair early language acquisition,^{95–97} but the child's home environment has a greater impact on outcomes⁹⁸; recent randomized trials^{41,99,100} suggest no impact on children with OME who are not at risk as identified by screening or surveillance.

Studies examining hearing sensitivity in children with OME report that average pure-tone hearing loss at 4 frequencies (500, 1000, 2000, and 4000 Hz) ranges from normal hearing to moderate hearing loss (0–55 dB). The 50th percentile is an ~25-dB HL, and ~20% of ears exceed 35-dB HL.^{101,102} Unilateral OME with hearing loss results in overall poorer binaural hearing than in infants with normal middle-ear function bilaterally.^{103,104} However, based on limited research, there is evidence that children experiencing the greatest conductive hearing loss for the longest periods may be more likely to exhibit developmental and academic sequelae.^{1,95,105}

Initial hearing testing for children 4 years old or older can be done in the primary care setting.¹⁰⁶ Testing should be performed in a quiet environment, preferably in a separate closed or sound-proofed area set aside specifically for that purpose. Conventional audiometry with earphones is performed with a fail criterion of more than 20-dB HL at 1 or more frequencies (500, 1000, 2000, and 4000 Hz) in either ear.^{106,107} Methods not recommended as substitutes for primary care hearing testing include tympanometry and pneumatic otoscopy,¹⁰² caregiver judgment regarding hearing loss,^{108,109} speech audiometry, and tuning forks, acoustic reflectometry, and behavioral observation.¹

Comprehensive audiologic evaluation is recommended for children who fail primary care testing, are less than 4 years old, or cannot be tested in the primary care setting. Audiologic assessment includes evaluating air-conduction and bone-conduction thresholds for pure tones, speech-detection or speech-recognition thresholds,¹⁰² and measuring speech understanding if possible.⁹⁴ The method of assessment depends on the developmental age of the child and might include visual reinforcement or conditioned orienting-response audiometry for infants 6 to 24 months old, play audiometry for children 24 to 48 months old, or conventional screening audiometry for children 4 years old and older.¹⁰⁶ The auditory brainstem response and otoacoustic emission are tests of auditory pathway structural integrity, not hearing, and should not substitute for behavioral pure-tone audiometry.¹⁰⁶

Language Testing

Language testing should be conducted for children with hearing loss (pure-tone average more than 20-dB HL on comprehensive audiometric evaluation). Testing for language delays is important, because communication is integral to all aspects of human functioning. Young children with speech and language delays during the preschool years are at risk for continued communication problems and later delays in reading and writing.^{110–112} In one study, 6% to 8% of children 3 years old and 2% to 13% of kindergartners had language impairment.¹¹³ Language intervention can improve communication and other functional outcomes for children with histories of OME.¹¹⁴

Children who experience repeated and persistent episodes of OME and associated hearing loss during early childhood may be at a disadvantage for learning speech and language.^{79,115} Although Shekelle et al² concluded that there was no evidence to support the concern that OME during the first 3 years of life was related to later receptive or expressive language, this meta-analysis should be interpreted cautiously, because it did not examine specific language domains such as vocabulary and the independent variable was OME and not hearing loss. Other meta-analyses^{79,115} have suggested at most a small negative association of OME and hearing loss on children's receptive and expressive language through the elementary school years. The clinical significance of these effects for language and learning is unclear for the child not at risk. For example, in one randomized trial,¹⁰⁰ prompt insertion of tympanostomy tubes for OME did not improve developmental outcomes at 3 years old regardless of baseline hearing. In another randomized trial,¹¹⁶ however, prompt tube insertion achieved small benefits for children with bilateral OME and hearing loss.

Clinicians should ask the parent or caregiver about specific concerns regarding their child's language development. Children's speech and language can be tested at ages 6 to 36 months by direct engagement of a child and interviewing the parent using the Early Language Milestone Scale.¹¹⁷ Other approaches require interviewing only the child's parent or caregiver, such

as the MacArthur Communicative Development Inventory¹¹⁸ and the Language Development Survey.¹¹⁹ For older children, the Denver Developmental Screening Test II¹²⁰ can be used to screen general development including speech and language. Comprehensive speech and language evaluation is recommended for children who fail testing or whenever the child's parent or caregiver expresses concern.¹²¹

Evidence Profile: Hearing and Language

- Aggregate evidence quality: B, diagnostic studies with minor limitations; C, observational studies.
- Benefit: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes.
- Harm: parental anxiety, direct and indirect costs of assessment, and/or false-positive results.
- Balance of benefit and harm: preponderance of benefit over harm.
- Policy level: recommendation.

7. SURVEILLANCE: CHILDREN WITH PERSISTENT OME WHO ARE NOT AT RISK SHOULD BE REEXAMINED AT 3- TO 6-MONTH INTERVALS UNTIL THE EFFUSION IS NO LONGER PRESENT, SIGNIFICANT HEARING LOSS IS IDENTIFIED, OR STRUCTURAL ABNORMALITIES OF THE EARDRUM OR MIDDLE EAR ARE SUSPECTED

This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.

If OME is asymptomatic and is likely to resolve spontaneously, intervention is unnecessary even if OME persists for more than 3 months. The clinician should determine whether risk factors exist that would predispose the child to undesirable sequelae or predict nonresolution of the effusion. As long as OME persists, the child is at risk for sequelae and must be reevaluated periodically for factors that would prompt intervention.

The 1994 OME guideline¹ recommended surgery for OME persisting 4 to 6 months with hearing loss but requires reconsideration because of later data on tubes and developmental sequelae.¹²² For example, selecting surgical candidates using duration-based criteria (eg, OME >3 months or exceeding a cumulative threshold) does not improve developmental outcomes in infants and toddlers who are not at risk.^{41,42,99,100} Additionally, the 1994 OME guideline did not specifically address managing effusion without significant hearing loss persisting more than 6 months.

Asymptomatic OME usually resolves spontaneously, but resolution rates decrease the longer the effusion has been present,^{36,76,77} and relapse is common.¹²³ Risk factors that make spontaneous resolution less likely include^{124,125}:

- Onset of OME in the summer or fall season
- Hearing loss more than 30-dB HL in the better-hearing ear

- History of prior tympanostomy tubes
- Not having had an adenoidectomy

Children with chronic OME are at risk for structural damage of the tympanic membrane¹²⁶ because the effusion contains leukotrienes, prostaglandins, and arachidonic acid metabolites that invoke a local inflammatory response.¹²⁷ Reactive changes may occur in the adjacent tympanic membrane and mucosal linings. A relative underventilation of the middle ear produces a negative pressure that predisposes to focal retraction pockets, generalized atelectasis of the tympanic membrane, and cholesteatoma.

Structural integrity is assessed by carefully examining the entire tympanic membrane, which, in many cases, can be accomplished by the primary care clinician using a handheld pneumatic otoscope. A search should be made for retraction pockets, ossicular erosion, and areas of atelectasis or atrophy. If there is any uncertainty that all observed structures are normal, the patient should be examined by using an otomicroscope. All children with these tympanic membrane conditions, regardless of OME duration, should have a comprehensive audiologic evaluation.

Conditions of the tympanic membrane that generally mandate inserting a tympanostomy tube are posterosuperior retraction pockets, ossicular erosion, adhesive atelectasis, and retraction pockets that accumulate keratin debris. Ongoing surveillance is mandatory, because the incidence of structural damage increases with effusion duration.¹²⁸

As noted in recommendation 6, children with persistent OME for 3 months or longer should have their hearing tested. Based on these results, clinicians can identify 3 levels of action based on HLs obtained for the better-hearing ear using earphones or in sound field using speakers if the child is too young for ear-specific testing.

1. HLs of ≥ 40 dB (at least a moderate hearing loss): A comprehensive audiologic evaluation is indicated if not previously performed. If moderate hearing loss is documented and persists at this level, surgery is recommended, because persistent hearing loss of this magnitude that is permanent in nature has been shown to impact speech, language, and academic performance.^{129–131}
2. HLs of 21 to 39 dB (mild hearing loss): A comprehensive audiologic evaluation is indicated if not previously performed. Mild sensorineural hearing loss has been associated with difficulties in speech, language, and academic performance in school,^{129,132} and persistent mild conductive hearing loss from OME may have a similar impact. Further management should be individualized based on effusion duration, severity of hearing loss, and parent or caregiver preference and may include strategies to optimize the listening and learning environment (Table 4) or surgery. Repeat hearing testing should be performed in 3 to 6 months if OME persists at follow-up evaluation or tympanostomy tubes have not been placed.
3. HLs of ≤ 20 dB (normal hearing): A repeat hearing test should be performed in 3 to 6 months if OME persists at follow-up evaluation.

TABLE 4. Strategies for Optimizing the Listening-Learning Environment for Children With OME and Hearing Loss*

Get within 3 feet of the child before speaking.
Turn off competing audio signals such as unnecessary music and television in the background.
Face the child and speak clearly, using visual clues (hands, pictures) in addition to speech.
Slow the rate, raise the level, and enunciate speech directed at the child.
Read to or with the child, explaining pictures and asking questions.
Repeat words, phrases, and questions when misunderstood.
Assign preferential seating in the classroom near the teacher.
Use a frequency-modulated personal- or sound-field-amplification system in the classroom.

* Modified with permission from Roberts et al.^{78,79}

In addition to hearing loss and speech or language delay, other factors may influence the decision to intervene for persistent OME. Roberts et al^{98,133} showed that the caregiving environment is more strongly related to school outcome than was OME or hearing loss. Risk factors for delays in speech and language development caused by a poor caregiving environment included low maternal educational level, unfavorable child care environment, and low socioeconomic status. In such cases, these factors may be additive to the hearing loss in affecting lower school performance and classroom behavior problems.

Persistent OME may be associated with physical or behavioral symptoms including hyperactivity, poor attention, and behavioral problems in some studies^{134–136} and reduced child quality of life.⁴⁶ Conversely, young children randomized to early versus late tube insertion for persistent OME showed no behavioral benefits from early surgery.^{41,100} Children with chronic OME also have significantly poorer vestibular function and gross motor proficiency when compared with non-OME controls.^{48–50} Moreover, vestibular function, behavior, and quality of life can improve after tympanostomy tube insertion.^{47,137,138} Other physical symptoms of OME that, if present and persistent, may warrant surgery include otalgia, unexplained sleep disturbance, and coexisting recurrent AOM. Tubes reduce the absolute incidence of recurrent AOM by ~1 episode per child per year, but the relative risk reduction is 56%.¹³⁹

The risks of continued observation of children with OME must be balanced against the risks of surgery. Children with persistent OME examined regularly at 3- to 6-month intervals, or sooner if OME-related symptoms develop, are most likely at low risk for physical, behavioral, or developmental sequelae of OME. Conversely, prolonged watchful waiting of OME is not appropriate when regular surveillance is impossible or when the child is at risk for developmental sequelae of OME because of comorbidities (Table 3). For these children, the risks of anesthesia and surgery (see recommendation 9) may be less than those of continued observation.

Evidence Profile: Surveillance

- Aggregate evidence quality: C, observational studies and some randomized trials.

- Benefit: avoiding interventions that do not improve outcomes.
- Harm: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, and/or failing to detect significant signs or symptoms that require intervention.
- Balance of benefit and harm: preponderance of benefit over harm.
- Policy level: recommendation.

8. REFERRAL: WHEN CHILDREN WITH OME ARE REFERRED BY THE PRIMARY CARE CLINICIAN FOR EVALUATION BY AN OTOLARYNGOLOGIST, AUDIOLOGIST, OR SPEECH-LANGUAGE PATHOLOGIST, THE REFERRING CLINICIAN SHOULD DOCUMENT THE EFFUSION DURATION AND SPECIFIC REASON FOR REFERRAL (EVALUATION, SURGERY) AND PROVIDE ADDITIONAL RELEVANT INFORMATION SUCH AS HISTORY OF AOM AND DEVELOPMENTAL STATUS OF THE CHILD

This option is based on panel consensus and a preponderance of benefit over harm.

This recommendation emphasizes the importance of communication between the referring primary care clinician and the otolaryngologist, audiologist, and speech-language pathologist. Parents and caregivers may be confused and frustrated when a recommendation for surgery is made for their child because of conflicting information about alternative management strategies. Choosing among management options is facilitated when primary care physicians and advanced-practice nurses who best know the patient's history of ear problems and general medical status provide the specialist with accurate information. Although there are no studies showing improved outcomes from better documentation of OME histories, there is a clear need for better mechanisms to convey information and expectations from primary care clinicians to consultants and subspecialists.^{140–142}

When referring a child for evaluation to an otolaryngologist, the primary care physician should explain the following to the parent or caregiver of the patient:

- Reason for referral: Explain that the child is seeing an otolaryngologist for evaluation, which is likely to include ear examination and audiologic testing, and not necessarily simply to be scheduled for surgery.
- What to expect: Explain that surgery may be recommended, and let the parent know that the otolaryngologist will explain the options, benefits, and risks further.
- Decision-making process: Explain that there are many alternatives for management and that surgical decisions are elective; the parent or caregiver should be encouraged to express to the surgeon any concerns he or she may have about the recommendations made.

When referring a child to an otolaryngologist, audiologist, or speech-language pathologist, the mini-

mum information that should be conveyed in writing includes:

- Duration of OME: State how long fluid has been present.
- Laterality of OME: State whether one or both ears have been affected.
- Results of prior hearing testing or tympanometry.
- Suspected speech or language problems: State whether there had been a delay in speech and language development or whether the parent or a caregiver has expressed concerns about the child's communication abilities, school achievement, or attentiveness.
- Conditions that might exacerbate the deleterious effects of OME: State whether the child has conditions such as permanent hearing loss, impaired cognition, developmental delays, cleft lip or palate, or an unstable or nonsupportive family or home environment.
- AOM history: State whether the child has a history of recurrent AOM.

Additional medical information that should be provided to the otolaryngologist by the primary care clinician includes:

- Parental attitude toward surgery: State whether the parents have expressed a strong preference for or against surgery as a management option.
- Related conditions that might require concomitant surgery: State whether there have been other conditions that might warrant surgery if the child is going to have general anesthesia (eg, nasal obstruction and snoring that might be an indication for adenoidectomy or obstructive breathing during sleep that might mean tonsillectomy is indicated).
- General health status: State whether there are any conditions that might present problems for surgery or administering general anesthesia, such as congenital heart abnormality, bleeding disorder, asthma or reactive airway disease, or family history of malignant hyperthermia.

After evaluating the child, the otolaryngologist, audiologist, or speech-language pathologist should inform the referring physician regarding his or her diagnostic impression, plans for additional assessment, and recommendations for ongoing monitoring and management.

Evidence Profile: Referral

- Aggregate evidence quality: C, observational studies.
- Benefit: better communication and improved decision-making.
- Harm: confidentiality concerns, administrative burden, and/or increased parent or caregiver anxiety.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: option.

9. SURGERY: WHEN A CHILD BECOMES A SURGICAL CANDIDATE, TYMPANOSTOMY TUBE INSERTION IS THE PREFERRED INITIAL PROCEDURE; ADENOIDECTOMY SHOULD NOT BE PERFORMED UNLESS A DISTINCT INDICATION EXISTS (NASAL OBSTRUCTION, CHRONIC ADENOIDITIS). REPEAT SURGERY CONSISTS OF ADENOIDECTOMY PLUS MYRINGOTOMY, WITH OR WITHOUT TUBE INSERTION. TONSILLECTOMY ALONE OR MYRINGOTOMY ALONE SHOULD NOT BE USED TO TREAT OME

This recommendation is based on randomized, controlled trials with a preponderance of benefit over harm.

Surgical candidacy for OME largely depends on hearing status, associated symptoms, the child's developmental risk (Table 3), and the anticipated chance of timely spontaneous resolution of the effusion. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damage to the tympanic membrane or middle ear. Ultimately, the recommendation for surgery must be individualized based on consensus between the primary care physician, otolaryngologist, and parent or caregiver that a particular child would benefit from intervention. Children with OME of any duration who are at risk are candidates for earlier surgery.

Tympanostomy tubes are recommended for initial surgery because randomized trials show a mean 62% relative decrease in effusion prevalence and an absolute decrease of 128 effusion days per child during the next year.^{139,143–145} HLs improve by a mean of 6 to 12 dB while the tubes remain patent.^{146,147} Adenoidectomy plus myringotomy (without tube insertion) has comparable efficacy in children 4 years old or older¹⁴³ but is more invasive, with additional surgical and anesthetic risks. Similarly, the added risk of adenoidectomy outweighs the limited, short-term benefit for children 3 years old or older without prior tubes.¹⁴⁸ Consequently, adenoidectomy is not recommended for initial OME surgery unless a distinct indication exists, such as adenoiditis, postnasal obstruction, or chronic sinusitis.

Approximately 20% to 50% of children who have had tympanostomy tubes have OME relapse after tube extrusion that may require additional surgery.^{144,145,149} When a child needs repeat surgery for OME, adenoidectomy is recommended (unless the child has an overt or submucous cleft palate), because it confers a 50% reduction in the need for future operations.^{143,150,151} The benefit of adenoidectomy is apparent at 2 years old,¹⁵⁰ greatest for children 3 years old or older, and independent of adenoid size.^{143,151,152} Myringotomy is performed concurrent with adenoidectomy. Myringotomy plus adenoidectomy is effective for children 4 years old or older,¹⁴³ but tube insertion is advised for younger children, when potential relapse of effusion must be minimized (eg, children at risk) or pronounced inflammation of the tympanic membrane and middle-ear mucosa is present.

Tonsillectomy or myringotomy alone (without adenoidectomy) is not recommended to treat OME. Although tonsillectomy is either ineffective¹⁵² or of limited efficacy,^{148,150} the risks of hemorrhage (~2%) and additional hospitalization outweigh any potential benefits unless a distinct indication for tonsillectomy exists. Myringotomy alone, without tube placement or adenoidectomy, is ineffective for chronic OME,^{144,145} because the incision closes within several days. Laser-assisted myringotomy extends the ventilation period several weeks,¹⁵³ but randomized trials with concurrent controls have not been conducted to establish efficacy. In contrast, tympanostomy tubes ventilate the middle ear for an average of 12 to 14 months.^{144,145}

Anesthesia mortality has been reported to be ~1:50 000 for ambulatory surgery,¹⁵⁴ but the current fatality rate may be lower.¹⁵⁵ Laryngospasm and bronchospasm occur more often in children receiving anesthesia than adults. Tympanostomy tube sequelae are common¹⁵⁶ but are generally transient (otorrhea) or do not affect function (tympanosclerosis, focal atrophy, or shallow retraction pocket). Tympanic membrane perforations, which may require repair, are seen in 2% of children after placement of short-term (grommet-type) tubes and 17% after long-term tubes.¹⁵⁶ Adenoidectomy has a 0.2% to 0.5% incidence of hemorrhage^{150,157} and 2% incidence of transient velopharyngeal insufficiency.¹⁴⁸ Other potential risks of adenoidectomy, such as nasopharyngeal stenosis and persistent velopharyngeal insufficiency, can be minimized with appropriate patient selection and surgical technique.

There is a clear preponderance of benefit over harm when considering the impact of surgery for OME on effusion prevalence, HLs, subsequent incidence of AOM, and the need for reoperation after adenoidectomy. Information about adenoidectomy in children less than 4 years old, however, remains limited. Although the cost of surgery and anesthesia is nontrivial, it is offset by reduced OME and AOM after tube placement and by reduced need for reoperation after adenoidectomy. Approximately 8 adenoidectomies are needed to avoid a single instance of tube reinsertion; however, each avoided surgery probably represents a larger reduction in the number of AOM and OME episodes, including those in children who did not require additional surgery.¹⁵⁰

Evidence Profile: Surgery

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations.
- Benefit: improved hearing, reduced prevalence of OME, reduced incidence of AOM, and less need for additional tube insertion (after adenoidectomy).
- Harm: risks of anesthesia and specific surgical procedures; sequelae of tympanostomy tubes.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

10. CAM: NO RECOMMENDATION IS MADE REGARDING CAM AS A TREATMENT FOR OME

There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.

The 1994 OME guideline¹ made no recommendation regarding CAM as a treatment for OME, and no subsequent controlled studies have been published to change this conclusion. The current statement of “no recommendation” is based on the lack of scientific evidence documenting efficacy plus the balance of benefit and harm.

Evidence concerning CAM is insufficient to determine whether the outcomes achieved for OME differ from those achieved by watchful waiting and spontaneous resolution. There are no randomized, controlled trials with adequate sample sizes on the efficacy of CAM for OME. Although many case reports and subjective reviews on CAM treatment of AOM were found, little is published on OME treatment or prevention. Homeopathy¹⁵⁸ and chiropractic treatments¹⁵⁹ were assessed in pilot studies with small numbers of patients that failed to show clinically or statistically significant benefits. Consequently, there is no research base on which to develop a recommendation concerning CAM for OME.

The natural history of OME in childhood (discussed previously) is such that almost any intervention can be “shown” to have helped in an anecdotal, uncontrolled report or case series. The efficacy of CAM or any other intervention for OME can only be shown with parallel-group, randomized, controlled trials with valid diagnostic methods and adequate sample sizes. Unproved modalities that have been claimed to provide benefit in middle-ear disease include osteopathic and chiropractic manipulation, dietary exclusions (such as dairy), herbal and other dietary supplements, acupuncture, traditional Chinese medicine, and homeopathy. None of these modalities, however, have been subjected yet to a published, peer-reviewed, clinical trial.

The absence of any published clinical trials also means that all reports of CAM adverse effects are anecdotal. A systematic review of recent evidence¹⁶⁰ found significant serious adverse effects of unconventional therapies for children, most of which were associated with inadequately regulated herbal medicines. One report on malpractice liability associated with CAM therapies¹⁶¹ did not address childhood issues specifically. Allergic reactions to echinacea occur but seem to be rare in children.¹⁶² A general concern about herbal products is the lack of any governmental oversight into product quality or purity.^{160,163,164} Additionally, herbal products may alter blood levels of allopathic medications, including anticoagulants. A possible concern with homeopathy is the worsening of symptoms, which is viewed as a positive, early sign of homeopathic efficacy. The adverse effects of manipulative therapies (such as chiropractic treatments and osteopathy) in children are difficult to assess because of scant evidence, but a case series of 332 children treated for AOM or OME with chiropractic manipulation did not mention any

side effects.¹⁶⁵ Quadriplegia has been reported, however, after spinal manipulation in an infant with torticollis.¹⁶⁶

Evidence Profile: CAM

- Aggregate evidence quality: D, case series without controls.
- Benefit: not established.
- Harm: potentially significant depending on the intervention.
- Benefits-harms assessment: uncertain balance of benefit and harm.
- Policy level: no recommendation.

11. ALLERGY MANAGEMENT: NO RECOMMENDATION IS MADE REGARDING ALLERGY MANAGEMENT AS A TREATMENT FOR OME

There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.

The 1994 OME guideline¹ made no recommendation regarding allergy management as a treatment for OME, and no subsequent controlled studies have been published to change this conclusion. The current statement of “no recommendation” is based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME plus the balance of benefit and harm.

A linkage between allergy and OME has long been speculated but to date remains unquantified. The prevalence of allergy among OME patients has been reported to range from less than 10% to more than 80%.¹⁶⁷ Allergy has long been postulated to cause OME through its contribution to eustachian tube dysfunction.¹⁶⁸ The cellular response of respiratory mucosa to allergens has been well studied. Therefore, similar to other parts of respiratory mucosa, the mucosa lining the middle-ear cleft is capable of an allergic response.^{169,170} Sensitivity to allergens varies among individuals, and atopy may involve neutrophils in type I allergic reactions that enhance the inflammatory response.¹⁷¹

The correlation between OME and allergy has been widely reported, but no prospective studies have examined the effects of immunotherapy compared with observation alone or other management options. Reports of OME cure after immunotherapy or food-elimination diets¹⁷² are impossible to interpret without concurrent control groups because of the favorable natural history of most untreated OME. The documentation of allergy in published reports has been defined inconsistently (medical history, physical examination, skin-prick testing, nasal smears, serum immunoglobulin E and eosinophil counts, inflammatory mediators in effusions). Study groups have been drawn primarily from specialist offices, likely lack heterogeneity, and are not representative of general medical practice.

Evidence Profile: Allergy Management

- Aggregate evidence quality: D, case series without controls.

- Benefit: not established.
- Harm: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: no recommendation.

RESEARCH NEEDS

Diagnosis

- Further standardize the definition of OME.
- Assess the performance characteristics of pneumatic otoscopy as a diagnostic test for OME when performed by primary care physicians and advanced-practice nurses in the routine office setting.
- Determine the optimal methods for teaching pneumatic otoscopy to residents and clinicians.
- Develop a brief, reliable, objective method for diagnosing OME.
- Develop a classification method for identifying the presence of OME for practical use by clinicians that is based on quantifiable tympanometric characteristics.
- Assess the usefulness of algorithms combining pneumatic otoscopy and tympanometry for detecting OME in clinical practice.
- Conduct additional validating cohort studies of acoustic reflectometry as a diagnostic method for OME, particularly in children less than 2 years old.

Child At Risk

- Better define the child with OME who is at risk for speech, language, and learning problems.
- Conduct large, multicenter, observational cohort studies to identify the child at risk who is most susceptible to potential adverse sequelae of OME.
- Conduct large, multicenter, observational cohort studies to analyze outcomes achieved with alternative management strategies for OME in children at risk.

Watchful Waiting

- Define the spontaneous resolution of OME in infants and young children (existing data are limited primarily to children 2 years old or older).
- Conduct large-scale, prospective cohort studies to obtain current data on the spontaneous resolution of newly diagnosed OME of unknown prior duration (existing data are primarily from the late 1970s and early 1980s).
- Develop prognostic indicators to identify the best candidates for watchful waiting.
- Determine whether the lack of impact from prompt insertion of tympanostomy tubes on speech and language outcomes seen in asymptomatic young children with OME identified by screening or intense surveillance can be generalized to older children with OME or to symptomatic children with OME referred for evaluation.

Medication

- Clarify which children, if any, should receive antimicrobials, steroids, or both for OME.
- Conduct a randomized, placebo-controlled trial on the efficacy of antimicrobial therapy, with or without concurrent oral steroid, in avoiding surgery in children with OME who are surgical candidates and have not received recent antimicrobials.
- Investigate the role of mucosal surface biofilms in refractory or recurrent OME and develop targeted interventions.

Hearing and Language

- Conduct longitudinal studies on the natural history of hearing loss accompanying OME.
- Develop improved methods for describing and quantifying the fluctuations in hearing of children with OME over time.
- Conduct prospective controlled studies on the relation of hearing loss associated with OME to later auditory, speech, language, behavioral, and academic sequelae.
- Develop reliable, brief, objective methods for estimating hearing loss associated with OME.
- Develop reliable, brief, objective methods for estimating speech or language delay associated with OME.
- Evaluate the benefits and administrative burden of language testing by primary care clinicians.
- Agree on the aspects of language that are vulnerable to or affected by hearing loss caused by OME, and reach a consensus on the best tools for measurement.
- Determine whether OME and associated hearing loss place children from special populations at greater risk for speech and language delays.

Surveillance

- Develop better tools for monitoring children with OME that are suitable for routine clinical care.
- Assess the value of new strategies for monitoring OME, such as acoustic reflectometry performed at home by the parent or caregiver, in optimizing surveillance.
- Improve our ability to identify children who would benefit from early surgery instead of prolonged surveillance.
- Promote early detection of structural abnormalities in the tympanic membrane associated with OME that may require surgery to prevent complications.
- Clarify and quantify the role of parent or caregiver education, socioeconomic status, and quality of the caregiving environment as modifiers of OME developmental outcomes.
- Develop methods for minimizing loss to follow-up during OME surveillance.

Surgery

- Define the role of adenoidectomy in children 3 years old or younger as a specific OME therapy.

- Conduct controlled trials on the efficacy of tympanostomy tubes for developmental outcomes in children with hearing loss, other symptoms, or speech and language delay.
- Conduct randomized, controlled trials of surgery versus no surgery that emphasize patient-based outcome measures (quality of life, functional health status) in addition to objective measures (effusion prevalence, HLs, AOM incidence, reoperation).
- Identify the optimal ways to incorporate parent or caregiver preference into surgical decision-making.

CAM

- Conduct randomized, controlled trials on the efficacy of CAM modalities for OME.
- Develop strategies to identify parents or caregivers who use CAM therapies for their child's OME, and encourage surveillance by the primary care clinician.

Allergy Management

- Evaluate the causal role of atopy in OME.
- Conduct randomized, controlled trials on the efficacy of allergy therapy for OME that are generalizable to the primary care setting.

CONCLUSIONS

This evidence-based practice guideline offers recommendations for identifying, monitoring, and managing the child with OME. The guideline emphasizes appropriate diagnosis and provides options for various management strategies including observation, medical intervention, and referral for surgical intervention. These recommendations should provide primary care physicians and other health care providers with assistance in managing children with OME.

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Otitis Media Clinical Practice Guidelines

Quick Reference Tools

- Action Statement Summary
 - The Diagnosis and Management of Acute Otitis Media
 - Otitis Media With Effusion
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Otitis Media
- Bonus Feature
 - Continuum Model for Otitis Media
- AAP Patient Education Handouts
 - *Acute Ear Infections and Your Child*
 - *Middle Ear Fluid and Your Child*

Action Statement Summary

The Diagnosis and Management of Acute Otitis Media

Key Action Statement 1A

Clinicians should diagnose acute otitis media (AOM) in children who present with moderate to severe bulging of the tympanic membrane (TM) *or* new onset of otorrhea not due to acute otitis externa. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 1B

Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 1C

Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 2

The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3A

Severe AOM: The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C [102.2°F] or higher). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3B

Nonsevere bilateral AOM in young children: The clinician should prescribe antibiotic therapy for bilateral AOM in children 6 months through 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3C

Nonsevere unilateral AOM in young children: The clinician should either prescribe antibiotic therapy *or* offer observa-

tion with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3D

Nonsevere AOM in older children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4A

Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4B

Clinicians should prescribe an antibiotic with additional β -lactamase coverage for AOM when a decision to treat with antibiotics has been made, *and* the child has received amoxicillin in the last 30 days *or* has concurrent purulent conjunctivitis, *or* has a history of recurrent AOM unresponsive to amoxicillin. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 4C

Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5A

Clinicians should not prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5B

Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year with 1 episode in the preceding 6 months). Evidence Quality: Grade B. Strength: Option.

Key Action Statement 6A

Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices of the Centers for Disease Control and prevention, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP). Evidence Quality: Grade B. Strength: Strong Recommendation.

Otitis Media With Effusion**1A. Pneumatic Otoscopy**

Clinicians should use pneumatic otoscopy as the primary diagnostic method for OME, and OME should be distinguished from AOM.

This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm.

1B. Tympanometry

Tympanometry can be used to confirm the diagnosis of OME.

This option is based on cohort studies and a balance of benefit and harm.

1C. Screening

Population-based screening programs for OME are not recommended in healthy, asymptomatic children.

This recommendation is based on randomized, controlled trials and cohort studies, with a preponderance of harm over benefit.

2. Documentation

Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME.

This recommendation is based on observational studies and strong preponderance of benefit over harm.

3. Child at Risk

Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and should evaluate hearing, speech, language, and need for intervention more promptly.

This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.

4. Watchful Waiting

Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown).

This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.

5. Medication

Antihistamines and decongestants are ineffective for OME and are not recommended for treatment; antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management.

This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.

6. Hearing and Language

Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; language testing should be conducted for children with hearing loss.

This recommendation is based on cohort studies and the preponderance of benefit over risk.

7. Surveillance

Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.

8. Referral

When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of AOM and developmental status of the child.

This option is based on panel consensus and a preponderance of benefit over harm.

9. Surgery

When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. tonsillectomy alone or myringotomy alone should not be used to treat OME.

This recommendation is based on randomized, controlled trials with a preponderance of benefit over harm.

10. CAM

No recommendation is made regarding CAM as a treatment for OME.

There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.

11. Allergy Management

No recommendation is made regarding allergy management as a treatment for OME.

There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.

Coding Quick Reference for Otitis Media

<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
381.01 Otitis media, acute, serous	H65.01 Acute serous otitis media, right ear H65.02 Left ear H65.03 Bilateral H65.04 Recurrent, right ear H65.05 Recurrent, left ear H65.06 Recurrent, bilateral
381.10 Otitis media, chronic, serous	H65.21 Chronic serous otitis media, right ear H65.22 Left ear H65.23 Bilateral
381.4 Otitis media with effusion	H65.91 Unspecified nonsuppurative otitis media, right ear H65.92 Left ear H65.93 Bilateral
382.00 Otitis media, acute, purulent	H66.001 Acute suppurative otitis media without spontaneous rupture of ear drum, right ear H66.002 Left ear H66.003 Bilateral H66.004 Recurrent, right ear H66.005 Recurrent, left ear H66.006 Recurrent, bilateral
382.01 Otitis media, acute, purulent, with rupture	H66.011 Acute suppurative otitis media with spontaneous rupture of ear drum, right ear H66.012 Left ear H66.013 Bilateral H66.014 Recurrent, right ear H66.015 Recurrent, left ear H66.016 Recurrent, bilateral
382.02 Otitis media, acute, purulent with associated condition (code underlying condition first)	H67.1 Otitis media in diseases classified elsewhere, right ear H67.2 Left ear H67.3 Bilateral
382.3 Otitis media, chronic, purulent	H66.3X1 Other chronic suppurative otitis media, right ear H66.3X2 Left ear H66.3X3 Bilateral

Continuum Model for Otitis Media

The following continuum model from *Coding for Pediatrics 2014* has been devised to express the various levels of service for otitis media. This model demonstrates the cumulative effect of the key criteria for each level of service using a single diagnosis as the common denominator. It also shows the importance of other variables, such as patient age, duration and severity of illness, social contexts, and comorbid conditions that often have key roles in pediatric cases.

Quick Reference for Codes Used in Continuum for Otitis Media				
E/M Code Level	History	Examination	MDM	Time
99211 ^a	NA	NA	NA	5 minutes
99212	Problem-focused	Problem-focused	Straightforward	10 minutes
99213	Expanded problem-focused	Expanded problem-focused	Low	15 minutes
99214	Detailed	Detailed	Moderate	25 minutes
99215	Comprehensive	Comprehensive	High	40 minutes
Abbreviations: E/M, evaluation and management; MDM; medical decision-making; NA, not applicable.				
^a Low level E/M service that may not require the presence of a physician.				

Adapted from American Academy of Pediatrics. *Coding for Pediatrics 2015: A Manual for Pediatric Documentation and Payment*. 20th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015.

Current Procedural Terminology (CPT®) 5-digit codes, nomenclature, and other data are copyright 2014 American Medical Association (AMA). All Rights Reserved.

Continuum Model for Otitis Media			
CPT Code Vignette	History	Physical Examination	Medical Decision-making
99211* Nursing evaluations Follow-up on serous fluid or hearing loss with tympanogram (Be sure to code tympanogram [92567] and/or audiogram [92551 series] in addition to 99211.) <i>*There are no required key components; however, the nurse must document his or her history, physical examination, and assessment to support medical necessity.</i>	1. Chief complaint 2. History of treatment		1. Completion of medication 2. No need for further therapy 3. No need for further follow-up
99212 Follow-up otitis media, uncomplicated with primary examination being limited to ears	Problem focused 1. Chief complaint 2. History of treatment 3. Difficulties with medication 4. Hearing status	Problem focused 1. Ears	Straightforward 1. Completion of medication 2. No need for further therapy 3. No need for further follow-up
99213 2-year-old presents with pinkeye and recent upper respiratory infection	Problem focused 1. Chief complaint 2. Brief history of present illness (HPI) plus pertinent review of systems (ROS) a. Symptoms b. Duration of illness c. Home management, including over-the-counter medications, and response d. Additional symptoms from ROS	Expanded problem focused 1. Ears 2. Nose 3. Throat 4. Conjunctiva 5. Overall appearance	Moderate or low complexity 1. Observation and nonprescription analgesics

Continuum Model for Otitis Media, continued

CPT Code Vignette	History	Physical Examination	Medical Decision-making
99214 An infant presents for suspected third episode within 2–3 months Infant presents with fever and cough	Detailed 1. Chief complaint 2. Detailed HPI plus pertinent ROS and pertinent past, family, and social history (PFSH) a. Symptoms of illness b. Fever, other signs c. Any other medications d. Allergies e. Frequency of similar infection in past and response to treatment f. Environmental factors (eg, tobacco exposure, child care) g. Immunization status h. Feeding history	Detailed 1. Overall appearance 2. Hydration status 3. Eyes 4. Ears 5. Nose 6. Throat 7. Lungs 8. Skin	Moderate complexity 1. Treatment including antibiotics and supportive care. 2. Consider/discuss tympanocentesis (69420 or 69421). 3. Hearing evaluation planned. 4. Discuss possible referral to an allergist or otolaryngologist for tympanostomy. 5. Discuss contributing environmental factors and supportive treatment.
99215 3-month-old presents with high fever, vomiting, irritability	Detailed 1. Chief complaint 2. Detailed HPI plus pertinent ROS and pertinent PFSH a. Symptoms of illness b. Fever, other signs c. Any other medications d. Allergies e. Frequency of similar infection in past and response to treatment f. Environmental factors (eg, tobacco exposure, child care) g. Immunization status h. Feeding history	Detailed 1. Overall appearance 2. Hydration status 3. Eyes 4. Ears 5. Nose 6. Throat 7. Lungs 8. Skin	High complexity 1. Laboratory tests: Consider a complete blood cell count with differential, blood culture, blood urea nitrogen, creatinine, electrolytes, urinalysis with culture, chest x-ray, and possible lumbar puncture based on history and clinical findings. 2. Antibiotic therapy: Consider parenteral antibiotics. 3. Consider hospitalization based on history, physical findings, and laboratory studies. 4. Determine need for follow-up (eg, reassess later in same day by phone or follow-up visit as well as later follow-up). 5. Attempt oral rehydration in office.

Continuum Model for Otitis Media, continued

CPT Code Vignette	History	Physical Examination	Medical Decision-making
99214 or 99215 NOTE: Depending on the variables (ie, time), this example could be reported as 99214 or 99215. Extended evaluation of child with chronic or recurrent otitis media NOTE: Time is the key factor when counseling and/or coordination of care are more than 50% of the face-to-face time with the patient. For 99214, the total visit time would be 25 minutes; for 99215, the total time is 40 minutes. You must document time spent on counseling and/or coordination of care and list the areas discussed.	Detailed History with extended HPI as in 99214, but complete ROS and PFSH	Detailed or comprehensive General or single organ system (ears, nose, mouth, and throat)	Moderate or high complexity Tests: audiometry and/or tympanometry Extensive discussion of treatment options including but not limited to 1. Continued episodic treatment with antibiotics 2. Myringotomy and tube placement 3. Adenoidectomy 4. Allergy evaluation 5. Steroid therapy with weighing of risk-benefit ratio of various therapies

Acute Ear Infections and Your Child

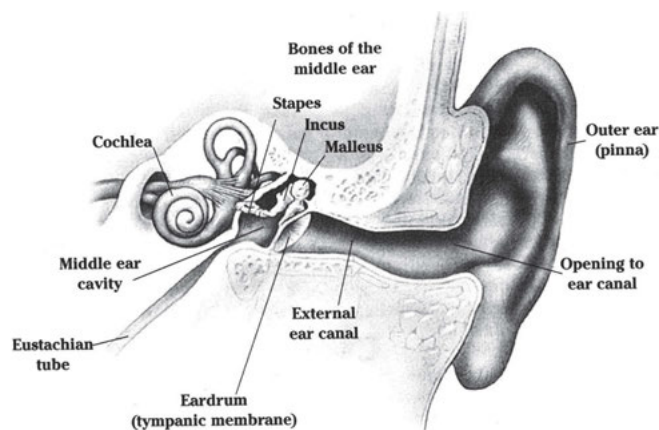
Next to the common cold, an ear infection is the most common childhood illness. In fact, most children have at least one ear infection by the time they are 3 years old. Many ear infections clear up without causing any lasting problems.

The following is information from the American Academy of Pediatrics about the symptoms, treatments, and possible complications of acute *otitis media*, a common infection of the middle ear.

How do ear infections develop?

The ear has 3 parts—the outer ear, middle ear, and inner ear. A narrow channel (eustachian tube) connects the middle ear to the back of the nose. When a child has a cold, nose or throat infection, or allergy, the mucus and fluid can enter the eustachian tube causing a buildup of fluid in the middle ear. If bacteria or a virus infects this fluid, it can cause swelling and pain in the ear. This type of ear infection is called *acute otitis media* (middle ear inflammation).

Often after the symptoms of acute otitis media clear up, fluid remains in the ear, creating another kind of ear problem called *otitis media with effusion* (middle ear fluid). This condition is harder to detect than acute otitis media because except for the fluid and usually some mild hearing loss, there is often no pain or other symptoms present. This fluid may last several months and, in most cases, disappears on its own. The child's hearing then returns to normal.



Cross-Section of the Ear

Is my child at risk for developing an ear infection?

Risk factors for developing childhood ear infections include

- **Age.** Infants and young children are more likely to get ear infections than older children. The size and shape of an infant's eustachian tube makes it easier for an infection to develop. Ear infections occur most often in children between 6 months and 3 years of age. Also, the younger a child is at the time of the first ear infection, the greater the chance he will have repeated infections.
- **Family history.** Ear infections can run in families. Children are more likely to have repeated middle ear infections if a parent or sibling also had repeated ear infections.
- **Colds.** Colds often lead to ear infections. Children in group child care settings have a higher chance of passing their colds to each other because they are exposed to more viruses from the other children.
- **Tobacco smoke.** Children who breathe in someone else's tobacco smoke have a higher risk of developing health problems, including ear infections.

How can I reduce the risk of an ear infection?

Some things you can do to help reduce your child's risk of getting an ear infection are

- Breastfeed instead of bottle-feed. Breastfeeding may decrease the risk of frequent colds and ear infections.
- Keep your child away from tobacco smoke, especially in your home or car.
- Throw away pacifiers or limit to daytime use, *if your child is older than 1 year.*
- Keep vaccinations up to date. Vaccines against bacteria (such as pneumococcal vaccine) and viruses (such as influenza vaccine) reduce the number of ear infections in children with frequent infections.

What are the symptoms of an ear infection?

Your child may have many symptoms during an ear infection. Talk with your pediatrician about the best way to treat your child's symptoms.

- **Pain.** The most common symptom of an ear infection is pain. Older children can tell you that their ears hurt. Younger children may only seem irritable and cry. You may notice this more during feedings because sucking and swallowing may cause painful pressure changes in the middle ear.
- **Loss of appetite.** Your child may have less of an appetite because of the ear pain.
- **Trouble sleeping.** Your child may have trouble sleeping because of the ear pain.
- **Fever.** Your child may have a temperature ranging from 100°F (normal) to 104°F.

- **Ear drainage.** You might notice yellow or white fluid, possibly blood-tinged, draining from your child's ear. The fluid may have a foul odor and will look different from normal earwax (which is orange-yellow or reddish-brown). Pain and pressure often decrease after this drainage begins, but this doesn't always mean that the infection is going away. If this happens it's not an emergency, but your child will need to see your pediatrician.
- **Trouble hearing.** During and after an ear infection, your child may have trouble hearing for several weeks. This occurs because the fluid behind the eardrum gets in the way of sound transmission. This is usually temporary and clears up after the fluid from the middle ear drains away.

Important: Your doctor *cannot* diagnose an ear infection over the phone; your child's eardrum must be examined by your doctor to confirm fluid buildup and signs of inflammation.

What causes ear pain?

There are other reasons why your child's ears may hurt besides an ear infection. The following can cause ear pain:

- An infection of the skin of the ear canal, often called "swimmer's ear"
- Reduced pressure in the middle ear from colds or allergies
- A sore throat
- Teething or sore gums
- Inflammation of the eardrum alone during a cold (without fluid buildup)

How are ear infections treated?

Because pain is often the first and most uncomfortable symptom of an ear infection, it's important to help comfort your child by giving her pain medicine. Acetaminophen and ibuprofen are over-the-counter (OTC) pain medicines that may help decrease much of the pain. Be sure to use the right dosage for your child's age and size. *Don't give aspirin to your child.* It has been associated with Reye syndrome, a disease that affects the liver and brain. There are also ear drops that may relieve ear pain for a short time. Ask your pediatrician whether these drops should be used. There is no need to use OTC cold medicines (decongestants and antihistamines), because they don't help clear up ear infections.

Not all ear infections require antibiotics. Some children who don't have a high fever and aren't severely ill may be observed without antibiotics. In most cases, pain and fever will improve in the first 1 to 2 days.

If your child is younger than 2 years, has drainage from the ear, has a fever higher than 102.5°F, seems to be in a lot of pain, is unable to sleep, isn't eating, or is acting ill, it's important to call your pediatrician. If your child is older than 2 years and your child's symptoms are mild, you may wait a couple of days to see if she improves.

Your child's ear pain and fever should improve or go away within 3 days of their onset. If your child's condition doesn't improve within 3 days, or worsens at any time, call your pediatrician. Your pediatrician may wish to see your child and may prescribe an antibiotic to take by mouth, if one wasn't given initially. If an antibiotic was already started, your child may need a different antibiotic. Be sure to follow your pediatrician's instructions closely.

If an antibiotic was prescribed, make sure your child finishes the entire prescription. If you stop the medicine too soon, some of the bacteria that caused the ear infection may still be present and cause an infection to start all over again.

As the infection starts to clear up, your child might feel a "popping" in the ears. This is a normal sign of healing. Children with ear infections don't need to stay home if they are feeling well, as long as a child care provider or someone at school can give them their medicine properly, if needed. If your child needs to travel in an airplane, or wants to swim, contact your pediatrician for specific instructions.

What are signs of hearing problems?

Because your child can have trouble hearing without other symptoms of an ear infection, watch for the following changes in behavior (especially during or after a cold):

- Talking more loudly or softly than usual
- Saying "huh?" or "what?" more than usual
- Not responding to sounds
- Having trouble understanding speech in noisy rooms
- Listening with the TV or radio turned up louder than usual

If you think your child may have difficulty hearing, call your pediatrician. Being able to hear and listen to others talk helps a child learn speech and language. This is especially important during the first few years of life.

Are there complications from ear infections?

Although it's very rare, complications from ear infections can develop, including the following:

- An infection of the inner ear that causes dizziness and imbalance (labyrinthitis)
- An infection of the skull behind the ear (mastoiditis)
- Scarring or thickening of the eardrum
- Loss of feeling or movement in the face (facial paralysis)
- Permanent hearing loss

It's normal for children to have several ear infections when they are young—even as many as 2 separate infections within a few months. Most ear infections that develop in children are minor. Recurring ear infections may be a nuisance, but they usually clear up without any lasting problems. With proper care and treatment, ear infections can usually be managed successfully. But, if your child has one ear infection after another for several months, you may want to talk about other treatment options with your pediatrician.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

American Academy
of Pediatrics



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Middle Ear Fluid and Your Child

The *middle* ear is the space behind the eardrum that is usually filled with air. When a child has middle ear fluid (otitis media with effusion), it means that a watery or mucus-like fluid has collected in the middle ear. *Otitis media* means *middle ear inflammation*, and *effusion* means *fluid*.

Middle ear fluid is **not** the same as an ear infection. An ear infection occurs when middle ear fluid is infected with viruses, bacteria, or both, often during a cold. Children with middle ear fluid have no signs or symptoms of infection. Most children don't have fever or severe pain, but may have mild discomfort or trouble hearing. About 90% of children get middle ear fluid at some time before age 5.

The following is information from the American Academy of Pediatrics about the causes, symptoms, risk reduction, testing, and treatments for middle ear fluid, as well as how middle ear fluid may affect your child's learning.

What causes middle ear fluid?

There is no one cause for middle ear fluid. Often your child's doctor may not know the cause. Middle ear fluid could be caused by

- A past ear infection
- A cold or flu
- Blockage of the eustachian tube (a narrow channel that connects the middle ear to the back of the nose)

What are the symptoms of middle ear fluid?

Many healthy children with middle ear fluid have little or no problems. They usually get better on their own. Often middle ear fluid is found at a regular checkup. Ear discomfort, if present, is usually mild. Your child may be irritable, rub his ears, or have trouble sleeping. Other symptoms include hearing loss, irritability, sleep problems, clumsiness, speech or language problems, and poor school performance. You may notice your child sitting closer to the TV or turning the sound up louder than usual. Sometimes it may seem like your child isn't paying attention to you, especially when at the playground or in a noisy environment.

Talk with your child's doctor if you are concerned about your child's hearing. Keep a record of your child's ear problems. Write down your child's name, child's doctor's name and number, date and type of ear problem or infection, treatment, and results. This may help your child's doctor find the cause of the middle ear fluid.

Can middle ear fluid affect my child's learning?

Some children with middle ear fluid are at risk for delays in speaking or may have problems with learning or schoolwork, especially children with

- Permanent hearing loss not caused by middle ear fluid
- Speech and language delays or disorders
- Developmental delay of social and communication skills disorders (for example, autism spectrum disorders)
- Syndromes that affect cognitive, speech, and language delays (for example, Down syndrome)
- Craniofacial disorders that affect cognitive, speech, and language delays (for example, cleft palate)
- Blindness or visual loss that can't be corrected

If your child is at risk and has ongoing middle ear fluid, her hearing, speech, and language should be checked.

How can I reduce the risk of middle ear fluid?

Children who live with smokers, attend group child care, or use pacifiers have more ear infections. Because some children who have middle ear infections later get middle ear fluid, you may want to

- Keep your child away from tobacco smoke.
- Keep your child away from children who are sick.
- Throw away pacifiers or limit to daytime use, *if your child is older than 1 year*.

Are there special tests to check for middle ear fluid?

Two tests that can check for middle ear fluid are *pneumatic otoscopy* and *tympanometry*. A pneumatic otoscope is the recommended test for middle ear fluid. With this tool, the doctor looks at the eardrum and uses air to see how well the eardrum moves. Tympanometry is another test for middle ear fluid that uses sound to see how well the eardrum moves. An eardrum with fluid behind it doesn't move as well as a normal eardrum. Your child must sit still for both tests; the tests are painless.

Because these tests don't check hearing level, a hearing test may be given, if needed. Hearing tests measure how well your child hears. Although hearing tests don't test for middle ear fluid, they can measure if the fluid is affecting your child's hearing level. The type of hearing test given depends on your child's age and ability to participate.

How can middle ear fluid be treated?

Middle ear fluid can be treated in several ways. Treatment options include observation and tube surgery or adenoid surgery. Because a treatment that works for one child may not work for another, your child's doctor can help you decide which treatment is best for your child and when you should see an ear, nose, and throat (ENT) specialist. If one treatment doesn't work, another treatment can be tried. Ask your child's doctor or ENT specialist about the costs, advantages, and disadvantages of each treatment.

When should middle ear fluid be treated?

Your child is more likely to need treatment for middle ear fluid if she has any of the following:

- Conditions placing her at risk for developmental delays (see "Can middle ear fluid affect my child's learning?")
- Fluid in both ears, especially if present more than 3 months
- Hearing loss or other significant symptoms (see "What are the symptoms of middle ear fluid?")

What treatments are not recommended?

A number of treatments are **not** recommended for young children with middle ear fluid.

- **Medicines** not recommended include antibiotics, decongestants, antihistamines, and steroids (by mouth or in nasal sprays). All of these have side effects and do not cure middle ear fluid.
- **Surgical treatments** not recommended include myringotomy (draining of fluid without placing a tube) and tonsillectomy (removal of the tonsils). If your child's doctor or ENT specialist suggests one of these surgeries, it may be for another medical reason. Ask your doctor why your child needs the surgery.

What about other treatment options?

There is no evidence that complementary and alternative medicine treatments or that treatment for allergies works to decrease middle ear fluid. Some of these treatments may be harmful and many are expensive.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

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- *Clinical Practice Guideline*
 - *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



- *Technical Report*

Readers of this clinical practice guideline are urged to review the technical report to enhance the evidence-based decision-making process. The full technical report is available following the clinical practice guideline and on the companion CD-ROM.

CLINICAL PRACTICE GUIDELINE

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

abstract

FREE

OBJECTIVE: To update the American Academy of Pediatrics clinical practice guideline regarding the diagnosis and management of acute bacterial sinusitis in children and adolescents.

METHODS: Analysis of the medical literature published since the last version of the guideline (2001).

RESULTS: The diagnosis of acute bacterial sinusitis is made when a child with an acute upper respiratory tract infection (URI) presents with (1) persistent illness (nasal discharge [of any quality] or daytime cough or both lasting more than 10 days without improvement), (2) a worsening course (worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement), or (3) severe onset (concurrent fever [temperature $\geq 39^{\circ}\text{C}/102.2^{\circ}\text{F}$] and purulent nasal discharge for at least 3 consecutive days). Clinicians should not obtain imaging studies of any kind to distinguish acute bacterial sinusitis from viral URI, because they do not contribute to the diagnosis; however, a contrast-enhanced computed tomography scan of the paranasal sinuses should be obtained whenever a child is suspected of having orbital or central nervous system complications. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course. The clinician should either prescribe antibiotic therapy or offer additional observation for 3 days to children with persistent illness. Amoxicillin with or without clavulanate is the first-line treatment of acute bacterial sinusitis. Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) or failure to improve within 72 hours of initial management. If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic or initiate antibiotic treatment of the child initially managed with observation.

CONCLUSIONS: Changes in this revision include the addition of a clinical presentation designated as “worsening course,” an option to treat immediately or observe children with persistent symptoms for 3 days before treating, and a review of evidence indicating that imaging is not necessary in children with uncomplicated acute bacterial sinusitis. *Pediatrics* 2013;132:e262–e280

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KEY WORDS

acute bacterial sinusitis, sinusitis, antibiotics, imaging, sinus aspiration

ABBREVIATIONS

AAP—American Academy of Pediatrics
AOM—acute otitis media
CT—computed tomography
PCV-13—13-valent pneumococcal conjugate vaccine
RABS—recurrent acute bacterial sinusitis
RCT—randomized controlled trial
URI—upper respiratory tract infection

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INTRODUCTION

Acute bacterial sinusitis is a common complication of viral upper respiratory infection (URI) or allergic inflammation. Using stringent criteria to define acute sinusitis, it has been observed that between 6% and 7% of children seeking care for respiratory symptoms has an illness consistent with this definition.¹⁻⁴

This clinical practice guideline is a revision of the clinical practice guideline published by the American Academy of Pediatrics (AAP) in 2001.⁵ It has been developed by a subcommittee of the Steering Committee on Quality Improvement and Management that included physicians with expertise in the fields of primary care pediatrics, academic general pediatrics, family practice, allergy, epidemiology and informatics, pediatric infectious diseases, pediatric otolaryngology, radiology, and pediatric emergency medicine. None of the participants had financial conflicts of interest, and only money from the AAP was used to fund the development of the guideline. The guideline will be reviewed in 5 years unless new evidence emerges that warrants revision sooner.

The guideline is intended for use in a variety of clinical settings (eg, office, emergency department, hospital) by

clinicians who treat pediatric patients. The data on which the recommendations are based are included in a companion technical report, published in the electronic pages.⁶ The Partnership for Policy Implementation has developed a series of definitions using accepted health information technology standards to assist in the implementation of this guideline in computer systems and quality measurement efforts. This document is available at: <http://www2.aap.org/informatics/PPI.html>.

This revision focuses on the diagnosis and management of acute sinusitis in children between 1 and 18 years of age. It does not apply to children with subacute or chronic sinusitis. Similar to the previous guideline, this document does not consider neonates and children younger than 1 year or children with anatomic abnormalities of the sinuses, immunodeficiencies, cystic fibrosis, or primary ciliary dyskinesia. The most significant areas of change from the 2001 guideline are in the addition of a clinical presentation designated as "worsening course," inclusion of new data on the effectiveness of antibiotics in children with acute sinusitis,⁴ and a review of evidence indicating that

imaging is not necessary to identify those children who will benefit from antimicrobial therapy.

METHODS

The Subcommittee on Management of Sinusitis met in June 2009 to identify research questions relevant to guideline revision. The primary goal was to update the 2001 report by identifying and reviewing additional studies of pediatric acute sinusitis that have been performed over the past decade.

Searches of PubMed were performed by using the same search term as in the 2001 report. All searches were limited to English-language and human studies. Three separate searches were performed to maximize retrieval of the most recent and highest-quality evidence for pediatric sinusitis. The first limited results to all randomized controlled trials (RCTs) from 1966 to 2009, the second to all meta-analyses from 1966 to 2009, and the third to all pediatric studies (limited to ages <18 years) published since the last technical report (1999–2009). Additionally, the Web of Science was queried to identify studies that cited the original AAP guidelines. This literature search was replicated in July 2010

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation Recommendation	

FIGURE 1

Levels of recommendations. Rec, recommendation.

and November 2012 to capture recently published studies. The complete results of the literature review are published separately in the technical report.⁶ In summary, 17 randomized studies of sinusitis in children were identified and reviewed. Only 3 trials met inclusion criteria. Because of significant heterogeneity among these studies, formal meta-analyses were not pursued.

The results from the literature review were used to guide development of the key action statements included in this document. These action statements were generated by using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor; Yale School of Medicine, New Haven, CT), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements.⁷ BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

The AAP policy statement “Classifying Recommendations for Clinical Practice Guidelines” was followed in designating

levels of recommendations (Fig 1).⁸ Definitions of evidence-based statements are provided in Table 1. This guideline was reviewed by multiple groups in the AAP and 2 external organizations. Comments were compiled and reviewed by the subcommittee, and relevant changes were incorporated into the guideline.

KEY ACTION STATEMENTS

Key Action Statement 1

Clinicians should make a presumptive diagnosis of acute bacterial sinusitis when a child with an acute URI presents with the following:

- **Persistent illness, ie, nasal discharge (of any quality) or daytime cough or both lasting more than 10 days without improvement;**

OR

- **Worsening course, ie, worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement;**

OR

- **Severe onset, ie, concurrent fever (temperature $\geq 39^{\circ}\text{C}/102.2^{\circ}\text{F}$) and purulent nasal discharge for at least 3 consecutive days (Evidence Quality: B; Recommendation).**

KAS Profile 1

Aggregate evidence quality: B

Benefit	Diagnosis allows decisions regarding management to be made. Children likely to benefit from antimicrobial therapy will be identified.
Harm	Inappropriate diagnosis may lead to unnecessary treatment. A missed diagnosis may lead to persistent infection or complications
Cost	Inappropriate diagnosis may lead to unnecessary cost of antibiotics. A missed diagnosis leads to cost of persistent illness (loss of time from school and work) or cost of caring for complications.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	None.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	Children aged <1 year or older than 18 years and with underlying conditions.
Strength	Recommendation.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

The purpose of this action statement is to guide the practitioner in making a diagnosis of acute bacterial sinusitis on the basis of stringent clinical criteria. To develop criteria to be used in distinguishing episodes of acute bacterial sinusitis from other common respiratory infections, it is helpful to describe the features of an uncomplicated viral URI. Viral URIs are usually characterized by nasal symptoms (discharge and congestion/obstruction) or cough or both. Most often, the nasal discharge begins as clear and watery. Often, however, the quality of nasal discharge changes during the course of the illness. Typically, the nasal discharge becomes thicker and more mucoid and may become purulent (thick, colored, and opaque) for several days. Then the situation reverses, with the purulent discharge becoming mucoid and then clear again or simply resolving. The transition from clear to purulent to clear again occurs in uncomplicated viral URIs without the use of antimicrobial therapy.

Fever, when present in uncomplicated viral URI, tends to occur early in the illness, often in concert with other constitutional symptoms such as headache and myalgias. Typically, the fever and constitutional symptoms disappear in the first 24 to 48 hours, and the respiratory symptoms become more prominent (Fig 2).

The course of most uncomplicated viral URIs is 5 to 7 days.^{9–12} As shown in Fig 2, respiratory symptoms usually peak in severity by days 3 to 6 and then begin to improve; however, resolving symptoms and signs may persist in some patients after day 10.^{9,10}

Symptoms of acute bacterial sinusitis and uncomplicated viral URI overlap considerably, and therefore it is their persistence without improvement that suggests a diagnosis of acute sinusitis.^{9,10,13} Such symptoms include

nasal discharge (of any quality: thick or thin, serous, mucoid, or purulent) or daytime cough (which may be worse at night) or both. Bad breath, fatigue, headache, and decreased appetite, although common, are not specific indicators of acute sinusitis.¹⁴ Physical examination findings are also not particularly helpful in distinguishing sinusitis from uncomplicated URIs. Erythema and swelling of the nasal turbinates are nonspecific findings.¹⁴ Percussion of the sinuses is not useful. Transillumination of the sinuses is difficult to perform correctly in children and has been shown to be unreliable.^{15,16} Nasopharyngeal cultures do not reliably predict the etiology of acute bacterial sinusitis.^{14,16}

Only a minority (~6%–7%) of children presenting with symptoms of URI will meet criteria for persistence.^{3,4,11} As a result, before diagnosing acute bacterial sinusitis, it is important for the practitioner to attempt to (1) differentiate between sequential episodes of uncomplicated viral URI (which may seem to coalesce in the mind of the patient or parent) from the onset of acute bacterial sinusitis with persistent symptoms and (2) establish whether the symptoms are clearly not improving.

A worsening course of signs and symptoms, termed “double sickening,” in the context of a viral URI is another presentation of acute bacterial sinusitis.^{13,17} Affected children experience substantial and acute worsening of

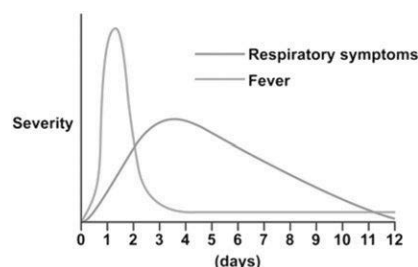


FIGURE 2
Uncomplicated viral URI.

respiratory symptoms (nasal discharge or nasal congestion or daytime cough) or a new fever, often on the sixth or seventh day of illness, after initial signs of recovery from an uncomplicated viral URI. Support for this definition comes from studies in children and adults, for whom antibiotic treatment of worsening symptoms after a period of apparent improvement was associated with better outcomes.⁴

Finally, some children with acute bacterial sinusitis may present with severe onset, ie, concurrent high fever (temperature $>39^{\circ}\text{C}$) and purulent nasal discharge. These children usually are ill appearing and need to be distinguished from children with uncomplicated viral infections that are unusually severe. If fever is present in uncomplicated viral URIs, it tends to be present early in the illness, usually accompanied by other constitutional symptoms, such as headache and myalgia.^{9,13,18} Generally, the constitutional symptoms resolve in the first 48 hours and then the respiratory symptoms become prominent. In most uncomplicated viral infections, including influenza, purulent nasal discharge does not appear for several days. Accordingly, it is the concurrent presentation of high fever and purulent nasal discharge for the first 3 to 4 days of an acute URI that helps to define the severe onset of acute bacterial sinusitis.^{13,16,18} This presentation in children is the corollary to acute onset of headache, fever, and facial pain in adults with acute sinusitis.

Allergic and nonallergic rhinitis are predisposing causes of some cases of acute bacterial sinusitis in childhood. In addition, at their onset, these conditions may be mistaken for acute bacterial sinusitis. A family history of atopic conditions, seasonal occurrences, or occurrences with exposure to common allergens and other

allergic diatheses in the index patient (eczema, atopic dermatitis, asthma) may suggest the presence of non-infectious rhinitis. The patient may have complaints of pruritic eyes and nasal mucosa, which will provide a clue to the likely etiology of the condition. On physical examination, there may be a prominent nasal crease, allergic shiners, cobblestoning of the conjunctiva or pharyngeal wall, or pale nasal mucosa as other indicators of the diagnosis.

Key Action Statement 2A

Clinicians should not obtain imaging studies (plain films, contrast-enhanced computed tomography [CT], MRI, or ultrasonography) to distinguish acute bacterial sinusitis from viral URI (Evidence Quality: B; Strong Recommendation).

suspected to have acute bacterial sinusitis, it is no longer recommended. The membranes that line the nose are continuous with the membranes (mucosa) that line the sinus cavities, the middle ear, the nasopharynx, and the oropharynx. When an individual experiences a viral URI, there is inflammation of the nasal mucosa and, often, the mucosa of the middle ear and paranasal sinuses as well. The continuity of the mucosa of the upper respiratory tract is responsible for the controversy regarding the usefulness of images of the paranasal sinuses in contributing to a diagnosis of acute bacterial sinusitis.

As early as the 1940s, observations were made regarding the frequency of abnormal sinus radiographs in healthy children without signs or symptoms of

skull became prevalent, several studies reported on incidental abnormalities of the paranasal sinuses that were observed in children.^{23,24} Gwaltney et al²⁵ showed striking abnormalities (including air-fluid levels) in sinus CT scans of young adults with uncomplicated colds. Manning et al²⁶ evaluated children undergoing either CT or MRI of the head for indications other than respiratory complaints or suspected sinusitis. Each patient underwent rhinoscopy and otoscopy before imaging and each patient's parent was asked to fill out a questionnaire regarding recent symptoms of URI. Sixty-two percent of patients overall had physical findings or history consistent with an upper respiratory inflammatory process, and 55% of the total group showed some abnormalities on sinus imaging; 33% showed pronounced mucosal thickening or an air-fluid level. Gordts et al²⁷ made similar observations in children undergoing MRI. Finally, Kristo et al²⁸ performed MRI in children with URIs and confirmed the high frequency (68%) of major abnormalities seen in the paranasal sinuses.

In summary, when the paranasal sinuses are imaged, either with plain radiographs, contrast-enhanced CT, or MRI in children with uncomplicated URI, the majority of studies will be significantly abnormal with the same kind of findings that are associated with bacterial infection of the sinuses. Accordingly, although normal radiographs or CT or MRI results can ensure that a patient with respiratory symptoms does not have acute bacterial sinusitis, an abnormal image cannot confirm the diagnosis. Therefore, it is not necessary to perform imaging in children with uncomplicated episodes of clinical sinusitis. Similarly, the high likelihood of an abnormal imaging result in a child with an uncomplicated URI indicates that radiographic studies

KAS Profile 2A

Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies.

Benefit	Avoids exposure to radiation and costs of studies. Avoids unnecessary therapy for false-positive diagnoses.
Harm	None.
Cost	Avoids cost of imaging.
Benefits-harm assessment	Exclusive benefit.
Value judgments	Concern for unnecessary radiation and costs.
Role of patient preference	Limited. Parents may value a negative study and avoidance of antibiotics as worthy of radiation but panel disagrees.
Intentional vagueness	None.
Exclusions	Patients with complications of sinusitis.
Strength	Strong recommendation.

The purpose of this key action statement is to discourage the practitioner from obtaining imaging studies in children with uncomplicated acute bacterial sinusitis. As emphasized in Key Action Statement 1, acute bacterial sinusitis in children is a diagnosis that is made on the basis of stringent clinical criteria that describe signs, symptoms, and temporal patterns of a URI. Although historically imaging has been used as a confirmatory or diagnostic modality in children

current respiratory disease.¹⁹ In addition, several investigators in the 1970s and 1980s observed that children with uncomplicated viral URI had frequent abnormalities of the paranasal sinuses on plain radiographs.^{20–22} These abnormalities were the same as those considered to be diagnostic of acute bacterial sinusitis (diffuse opacification, mucosal swelling of at least 4 mm, or an air-fluid level).¹⁶

As technology advanced and CT scanning of the central nervous system and

not be performed in an attempt to eliminate the diagnosis of sinusitis.

Key Action Statement 2B

Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI with contrast whenever a child is suspected of having orbital or central nervous system complications of acute bacterial sinusitis (Evidence Quality: B; Strong Recommendation).

KAS Profile 2B

Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies.	
Benefit	Determine presence of abscesses, which may require surgical intervention; avoid sequelae because of appropriate aggressive management.
Harm	Exposure to ionizing radiation for CT scans; need for sedation for MRI.
Cost	Direct cost of studies.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concern for significant complication that may be unrecognized and, therefore, not treated appropriately.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	None.
Strength	Strong recommendation.

The purpose of this key action statement is to have the clinician obtain contrast-enhanced CT images when children are suspected of having serious complications of acute bacterial sinusitis. The most common complication of acute sinusitis involves the orbit in children with ethmoid sinusitis who are younger than 5 years.^{29–31} Orbital complications should be suspected when the child presents with a swollen eye, especially if accompanied by proptosis or impaired function of the extraocular muscles. Orbital complications of acute sinusitis have been divided into 5 categories: sympathetic effusion, subperiosteal abscess, orbital cellulitis, orbital abscess, and cavernous sinus thrombosis.³² Although sympathetic effusion (inflammatory edema) is categorized as an

orbital complication, the site of infection remains confined to the sinus cavities; eye swelling is attributable to the impedance of venous drainage secondary to congestion within the ethmoid sinuses. Alternative terms for sympathetic effusion (inflammatory edema) are preseptal or periorbital cellulitis. The remaining “true” orbital complications are best visualized by contrast-enhanced CT scanning.

Intracranial complications of acute sinusitis, which are substantially less common than orbital complications, are more serious, with higher morbidity and mortality than those involving the orbit. Intracranial complications should be suspected in the patient who presents with a very severe headache, photophobia, seizures, or other focal neurologic findings. Intracranial complications include subdural empyema, epidural empyema, venous thrombosis, brain abscess, and meningitis.²⁹ Typically, patients with intracranial complications of acute bacterial sinusitis are previously healthy adolescent males with frontal sinusitis.^{33,34} There have been no head-to-head comparisons of the diagnostic accuracy of contrast-enhanced CT scanning to MRI with contrast in the evaluation

of orbital and intracranial complications of sinusitis in children. In general, the contrast-enhanced CT scan has been the preferred imaging study when complications of sinusitis are suspected.^{35,36} However, there are documented cases in which a contrast-enhanced CT scan has not revealed the abnormality responsible for the clinical presentation and the MRI with contrast has, especially for intracranial complications and rarely for orbital complications.^{37,38} Accordingly, the most recent appropriateness criteria from the American College of Radiology endorse both MRI with contrast and contrast-enhanced CT as complementary examinations when evaluating potential complications of sinusitis.³⁵ The availability and speed of obtaining the contrast-enhanced CT are desirable; however, there is increasing concern regarding exposure to radiation. The MRI, although very sensitive, takes longer than the contrast-enhanced CT and often requires sedation in young children (which carries its own risks). In older children and adolescents who may not require sedation, MRI with contrast, if available, may be preferred when intracranial complications are likely. Furthermore, MRI with contrast should be performed when there is persistent clinical concern or incomplete information has been provided by the contrast-enhanced CT scan.

Key Action Statement 3

Initial Management of Acute Bacterial Sinusitis

3A: “Severe onset and worsening course” acute bacterial sinusitis. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course (signs, symptoms, or both) (Evidence Quality: B; Strong Recommendation).

KAS Profile 3A

Aggregate evidence quality: B; randomized controlled trials with limitations.

Benefit	Increase clinical cures, shorten illness duration, and may prevent suppurative complications in a high-risk patient population.
Harm	Adverse effects of antibiotics.
Cost	Direct cost of therapy.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concern for morbidity and possible complications if untreated.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	None.
Strength	Strong recommendation.

3B: “Persistent illness.” The clinician should either prescribe antibiotic therapy OR offer additional outpatient observation for 3 days to children with persistent illness (nasal discharge of any quality or cough or both for at least 10 days without evidence of improvement) (Evidence Quality: B; Recommendation).

The purpose of this section is to offer guidance on initial management of persistent illness sinusitis by helping clinicians choose between the following 2 strategies:

1. Antibiotic therapy, defined as initial treatment of acute bacterial sinusitis with antibiotics, with the intent of starting antibiotic therapy as soon as possible after the encounter.

2. Additional outpatient observation, defined as initial management of acute bacterial sinusitis limited to continued observation for 3 days, with commencement of antibiotic therapy if either the child does not improve clinically within several days of diagnosis or if there is clinical worsening of the child's condition at any time.

In contrast to the 2001 AAP guideline,⁵ which recommended antibiotic therapy for all children diagnosed with acute bacterial sinusitis, this guideline allows for additional observation of children presenting with persistent illness (nasal discharge of any quality or daytime cough or both for at least 10 days without evidence of improvement). In both guidelines, however, children presenting with severe or worsening illness (which was not defined explicitly in the 2001 guideline⁵) are to receive antibiotic therapy. The rationale for this approach (Table 2) is discussed below.

Antibiotic Therapy for Acute Bacterial Sinusitis

In the United States, antibiotics are prescribed for 82% of children with acute sinusitis.³⁹ The rationale for antibiotic therapy of acute bacterial sinusitis is based on the recovery of bacteria in high density ($\geq 10^4$ colony-forming units/mL) in 70% of maxillary sinus aspirates obtained from children with a clinical syndrome characterized by persistent nasal discharge, daytime cough, or both.^{16,40} Children who present with severe-onset acute bacterial sinusitis are presumed to have bacterial infection, because a temperature of at least 39°C/102.2°F coexisting for at least 3 consecutive days with purulent nasal discharge is not consistent with the well-documented pattern of acute viral URI. Similarly, children with worsening-course acute bacterial sinusitis have a clinical course that is also not consistent with the steady improvement that characterizes an uncomplicated viral URI.^{9,10}

KAS Profile 3B

Aggregate evidence quality: B; randomized controlled trials with limitations.

Benefit	Antibiotics increase the chance of improvement or cure at 10 to 14 days (number needed to treat, 3–5); additional observation may avoid the use of antibiotics with attendant cost and adverse effects.
Harm	Antibiotics have adverse effects (number needed to harm, 3) and may increase bacterial resistance. Observation may prolong illness and delay start of needed antibiotic therapy.
Cost	Direct cost of antibiotics as well as cost of adverse reactions; indirect costs of delayed recovery when observation is used.
Benefits-harm assessment	Preponderance of benefit (because both antibiotic therapy and additional observation with rescue antibiotic, if needed, are appropriate management).
Value judgments	Role for additional brief observation period for selected children with persistent illness sinusitis, similar to what is recommended for acute otitis media, despite the lack of randomized trials specifically comparing additional observation with immediate antibiotic therapy and longer duration of illness before presentation.
Role of patient preference	Substantial role in shared decision-making that should incorporate illness severity, child's quality of life, and caregiver values and concerns.
Intentional vagueness	None.
Exclusions	Children who are excluded from randomized clinical trials of acute bacterial sinusitis, as defined in the text.
Strength	Recommendation.

Three RCTs have compared antibiotic therapy with placebo for the initial management of acute bacterial sinusitis in children. Two trials by Wald et al^{4,41} found an increase in cure or improvement after antibiotic therapy compared with placebo with a number needed to treat of 3 to 5 children. Most children in these studies had persistent acute bacterial sinusitis, but children with severe or worsening illness were also included. Conversely, Garbutt et al,⁴² who studied only children with persistent acute bacterial sinusitis, found no difference in outcomes for antibiotic versus placebo. Another RCT by Kristo et al,⁴³ often cited as showing no benefit from antibiotics for acute bacterial sinusitis, will not be considered further because of methodologic flaws, including weak entry criteria and inadequate dosing of antibiotic treatment. The guideline recommends antibiotic therapy for severe or worsening acute bacterial sinusitis because of the benefits revealed in RCTs^{4,41} and a theoretically higher risk of suppurative complications than for children who present with persistent symptoms. Orbital and intracranial complications of acute bacterial sinusitis have not been observed in RCTs, even when placebo was administered; however, sample sizes have inadequate power to preclude an increased risk. This risk, however, has caused some investigators to exclude children with severe acute bacterial sinusitis from trial entry.⁴²

Additional Observation for Persistent Onset Acute Bacterial Sinusitis

The guideline recommends either antibiotic therapy or an additional brief period of observation as initial management strategies for children with persistent acute bacterial sinusitis because, although there are benefits to antibiotic therapy (number needed to treat, 3–5), some children improve on their own, and the risk of suppurative

complications is low.^{4,41} Symptoms of persistent acute bacterial sinusitis may be mild and have varying effects on a given child's quality of life, ranging from slight (mild cough, nasal discharge) to significant (sleep disturbance, behavioral changes, school or child care absenteeism). The benefits of antibiotic therapy in some trials^{4,41} must also be balanced against an increased risk of adverse events (number need to harm, 3), most often self-limited diarrhea, but also including occasional rash.⁴

Choosing between antibiotic therapy or additional observation for initial management of persistent illness sinusitis presents an opportunity for shared decision-making with families (Table 2). Factors that might influence this decision include symptom severity, the child's quality of life, recent antibiotic use, previous experience or outcomes with acute bacterial sinusitis, cost of antibiotics, ease of administration, caregiver concerns about potential adverse effects of antibiotics, persistence of respiratory symptoms, or development of complications. Values and preferences expressed by the caregiver should be taken into consideration (Table 3).

Children with persistent acute bacterial sinusitis who received antibiotic therapy in the previous 4 weeks, those with concurrent bacterial infection (eg, pneumonia, suppurative cervical adenitis, group A streptococcal pharyngitis, or acute otitis media), those with actual or

suspected complications of acute bacterial sinusitis, or those with underlying conditions should generally be managed with antibiotic therapy. The latter group includes children with asthma, cystic fibrosis, immunodeficiency, previous sinus surgery, or anatomic abnormalities of the upper respiratory tract.

Limiting antibiotic use in children with persistent acute bacterial sinusitis who may improve on their own reduces common antibiotic-related adverse events, such as diarrhea, diaper dermatitis, and skin rash. The most recent RCT of acute bacterial sinusitis in children⁴ found adverse events of 44% with antibiotic and 14% with placebo.

Limiting antibiotics may also reduce the prevalence of resistant bacterial pathogens. Although this is always a desirable goal, no increase in resistant bacterial species was observed within the group of children treated with a single course of antimicrobial agents (compared with those receiving placebo) in 2 recent large studies of antibiotic versus placebo for children with acute otitis media.^{44,45}

Key Action Statement 4

Clinicians should prescribe amoxicillin with or without clavulanate as first-line treatment when a decision has been made to initiate antibiotic treatment of acute bacterial sinusitis (Evidence Quality: B; Recommendation).

KAS Profile 4

Aggregate evidence quality: B; randomized controlled trials with limitations.	
Benefit	Increase clinical cures with narrowest spectrum drug; stepwise increase in broadening spectrum as risk factors for resistance increase.
Harm	Adverse effects of antibiotics including development of hypersensitivity.
Cost	Direct cost of antibiotic therapy.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concerns for not encouraging resistance if possible.
Role of patient preference	Potential for shared decision-making that should incorporate the caregiver's experiences and values.
Intentional vagueness	None.
Exclusions	May include allergy or intolerance.
Strength	Recommendation.

TABLE 2 Recommendations for Initial Use of Antibiotics for Acute Bacterial Sinusitis

Clinical Presentation	Severe Acute Bacterial Sinusitis ^a	Worsening Acute Bacterial Sinusitis ^b	Persistent Acute Bacterial Sinusitis ^c
Uncomplicated acute bacterial sinusitis without coexisting illness	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation for 3 days ^d
Acute bacterial sinusitis with orbital or intracranial complications	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy
Acute bacterial sinusitis with coexisting acute otitis media, pneumonia, adenitis, or streptococcal pharyngitis	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy

^a Defined as temperature $\geq 39^{\circ}\text{C}$ and purulent (thick, colored, and opaque) nasal discharge present concurrently for at least 3 consecutive days.

^b Defined as nasal discharge or daytime cough with sudden worsening of symptoms (manifested by new-onset fever $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ or substantial increase in nasal discharge or cough) after having experienced transient improvement of symptoms.

^c Defined as nasal discharge (of any quality), daytime cough (which may be worse at night), or both, persisting for >10 days without improvement.

^d Opportunity for shared decision-making with the child's family; if observation is offered, a mechanism must be in place to ensure follow-up and begin antibiotics if the child worsens at any time or fails to improve within 3 days of observation.

The purpose of this key action statement is to guide the selection of antimicrobial therapy once the diagnosis of acute bacterial sinusitis has been made. The microbiology of acute bacterial sinusitis was determined nearly 30 years ago through direct maxillary sinus aspiration in children with compatible signs and symptoms. The major bacterial pathogens recovered at that time were *Streptococcus pneumoniae* in approximately 30% of children and nontypeable *Haemophilus influenzae* and *Moraxella catarrhalis* in approximately 20% each.^{16,40} Aspirates from the remaining 25% to 30% of children were sterile.

Maxillary sinus aspiration is rarely performed at the present time unless the course of the infection is unusually prolonged or severe. Although some authorities have recommended obtaining cultures from the middle meatus to determine the cause of a maxillary sinus infection, there are no data in children with acute bacterial sinusitis that have compared such cultures with cultures of a maxillary sinus aspirate. Furthermore, there are data indicating that the middle meatus in healthy children is commonly colonized

with *S pneumoniae*, *H influenzae*, and *M catarrhalis*.⁴⁶

Recent estimates of the microbiology of acute sinusitis have, of necessity, been based primarily on that of acute otitis media (AOM), a condition with relatively easy access to infective fluid through performance of tympanocentesis and one with a similar pathogenesis to acute bacterial sinusitis.^{47,48} The 3 most common bacterial pathogens recovered from the middle ear fluid of children with AOM are the same as those that have been associated with acute bacterial sinusitis: *S pneumoniae*, nontypeable *H influenzae*, and *M catarrhalis*.⁴⁹ The proportion of each has varied from study to study depending on criteria used for diagnosis of AOM, patient characteristics, and bacteriologic techniques. Recommendations since the year 2000 for the routine use in infants of 7-valent and, more recently, 13-valent pneumococcal conjugate vaccine (PCV-13) have been associated with a decrease in recovery of *S pneumoniae* from ear fluid of children with AOM and a relative increase in the incidence of infections attributable to *H influenzae*.⁵⁰ Thus, on the basis of the proportions of bacteria

found in middle ear infections, it is estimated that *S pneumoniae* and *H influenzae* are currently each responsible for approximately 30% of cases of acute bacterial sinusitis in children, and *M catarrhalis* is responsible for approximately 10%. These percentages are contingent on the assumption that approximately one-quarter of aspirates of maxillary sinusitis would still be sterile, as reported in earlier studies. *Staphylococcus aureus* is rarely isolated from sinus aspirates in children with acute bacterial sinusitis, and with the exception of acute maxillary sinusitis associated with infections of dental origin,⁵¹ respiratory anaerobes are also rarely recovered.^{40,52} Although *S aureus* is a very infrequent cause of acute bacterial sinusitis in children, it is a significant pathogen in the orbital and intracranial complications of sinusitis. The reasons for this discrepancy are unknown.

Antimicrobial susceptibility patterns for *S pneumoniae* vary considerably from community to community. Isolates obtained from surveillance centers nationwide indicate that, at the present time, 10% to 15% of upper respiratory tract isolates of *S pneumoniae* are nonsusceptible to penicillin^{53,54}; however, values for penicillin nonsusceptibility as high as 50% to 60% have been reported in some areas.^{55,56} Of the organisms that are resistant, approximately half are highly resistant to penicillin and the remaining half are intermediate in resistance.^{53,54,56–59} Between 10% and 42% of *H influenzae*^{56–59} and close to 100% of *M catarrhalis* are likely to be β -lactamase positive and nonsusceptible to amoxicillin. Because of dramatic geographic variability in the prevalence of β -lactamase-positive *H influenzae*, it is extremely desirable for the practitioner to be familiar with local patterns of susceptibility. Risk factors for the presence of organisms

likely to be resistant to amoxicillin include attendance at child care, receipt of antimicrobial treatment within the previous 30 days, and age younger than 2 years.^{50,55,60}

Amoxicillin remains the antimicrobial agent of choice for first-line treatment of uncomplicated acute bacterial sinusitis in situations in which antimicrobial resistance is not suspected. This recommendation is based on amoxicillin's effectiveness, safety, acceptable taste, low cost, and relatively narrow microbiologic spectrum. For children aged 2 years or older with uncomplicated acute bacterial sinusitis that is mild to moderate in degree of severity who do not attend child care and who have not been treated with an antimicrobial agent within the last 4 weeks, amoxicillin is recommended at a standard dose of 45 mg/kg per day in 2 divided doses. In communities with a high prevalence of nonsusceptible *S pneumoniae* (>10%, including intermediate- and high-level resistance), treatment may be initiated at 80 to 90 mg/kg per day in 2 divided doses, with a maximum of 2 g per dose.⁵⁵ This high-dose amoxicillin therapy is likely to achieve sinus fluid concentrations that are adequate to overcome the resistance of *S pneumoniae*, which is attributable to alteration in penicillin-binding proteins on the basis of data derived from patients with AOM.⁶¹ If, within the next several years after licensure of PCV-13, a continuing decrease in isolates of *S pneumoniae* (including a decrease in isolates of nonsusceptible *S pneumoniae*) and an increase in β -lactamase-producing *H influenzae* are observed, standard-dose amoxicillin-clavulanate (45 mg/kg per day) may be most appropriate.

Patients presenting with moderate to severe illness as well as those younger than 2 years, attending child care, or who have recently been treated with

an antimicrobial may receive high-dose amoxicillin-clavulanate (80–90 mg/kg per day of the amoxicillin component with 6.4 mg/kg per day of clavulanate in 2 divided doses with a maximum of 2 g per dose). The potassium clavulanate levels are adequate to inhibit all β -lactamase-producing *H influenzae* and *M catarrhalis*.^{56,59}

A single 50-mg/kg dose of ceftriaxone, given either intravenously or intramuscularly, can be used for children who are vomiting, unable to tolerate oral medication, or unlikely to be adherent to the initial doses of antibiotic.^{62–64} The 3 major bacterial pathogens involved in acute bacterial sinusitis are susceptible to ceftriaxone in 95% to 100% of cases.^{56,58,59} If clinical improvement is observed at 24 hours, an oral antibiotic can be substituted to complete the course of therapy. Children who are still significantly febrile or symptomatic at 24 hours may require additional parenteral doses before switching to oral therapy.

The treatment of patients with presumed allergy to penicillin has been controversial. However, recent publications indicate that the risk of a serious allergic reaction to second- and third-generation cephalosporins in patients with penicillin or amoxicillin allergy appears to be almost nil and no greater than the risk among patients without such allergy.^{65–67} Thus, patients allergic to amoxicillin with a non-type 1 (late or delayed, >72 hours) hypersensitivity reaction can safely be treated with cefdinir, cefuroxime, or cefpodoxime.^{66–68} Patients with a history of a serious type 1 immediate or accelerated (anaphylactoid) reaction to amoxicillin can also safely be treated with cefdinir, cefuroxime, or cefpodoxime. In both circumstances, clinicians may wish to determine individual tolerance by referral to an allergist for penicillin

and/or cephalosporin skin-testing before initiation of therapy.^{66–68} The susceptibility of *S pneumoniae* to cefdinir, cefpodoxime, and cefuroxime varies from 60% to 75%,^{56–59} and the susceptibility of *H influenzae* to these agents varies from 85% to 100%.^{56,58} In young children (<2 years) with a serious type 1 hypersensitivity to penicillin and moderate or more severe sinusitis, it may be prudent to use a combination of clindamycin (or linezolid) and cefixime to achieve the most comprehensive coverage against both resistant *S pneumoniae* and *H influenzae*. Linezolid has excellent activity against all *S pneumoniae*, including penicillin-resistant strains, but lacks activity against *H influenzae* and *M catarrhalis*. Alternatively, a quinolone, such as levofloxacin, which has a high level of activity against both *S pneumoniae* and *H influenzae*, may be prescribed.^{57,58} Although the use of quinolones is usually restricted because of concerns for toxicity, cost, and emerging resistance, their use in this circumstance can be justified.

Pneumococcal and *H influenzae* surveillance studies have indicated that resistance of these organisms to trimethoprim-sulfamethoxazole and azithromycin is sufficient to preclude their use for treatment of acute bacterial sinusitis in patients with penicillin hypersensitivity.^{56,58,59,69}

The optimal duration of antimicrobial therapy for patients with acute bacterial sinusitis has not received systematic study. Recommendations based on clinical observations have varied widely, from 10 to 28 days of treatment. An alternative suggestion has been made that antibiotic therapy be continued for 7 days after the patient becomes free of signs and symptoms.⁵ This strategy has the advantage of individualizing the treatment of each patient, results in a minimum course of 10 days, and

avoids prolonged antimicrobial therapy in patients who are asymptomatic and therefore unlikely to adhere to the full course of treatment.⁵

Patients who are acutely ill and appear toxic when first seen (see below) can be managed with 1 of 2 options. Consultation can be requested from an otolaryngologist for consideration of maxillary sinus aspiration (with appropriate analgesia/anesthesia) to obtain a sample of sinus secretions for Gram stain, culture, and susceptibility testing so that antimicrobial therapy can be adjusted precisely. Alternatively, inpatient therapy can be initiated with intravenous cefotaxime or ceftriaxone, with referral to an otolaryngologist if the patient's condition worsens or fails to show improvement within 48 hours. If a complication is suspected, management will differ depending on the site and severity.

A recent guideline was published by the Infectious Diseases Society of America for acute bacterial rhinosinusitis in children and adults.⁷⁰ Their recommendation for initial empirical antimicrobial therapy for acute bacterial sinusitis in children was amoxicillin-clavulanate based on the concern that there is an increasing prevalence of *H influenzae* as a cause of sinusitis since introduction of the pneumococcal conjugate vaccines and an increasing prevalence of β -lactamase production among these strains. In contrast, this guideline from the AAP allows either amoxicillin or amoxicillin-clavulanate as first-line empirical therapy and is therefore inclusive of the Infectious Diseases Society of America's recommendation. Unfortunately, there are scant data available regarding the precise microbiology of acute bacterial sinusitis in the post-PCV-13 era. Prospective surveillance of nasopharyngeal cultures may be helpful in completely

aligning these recommendations in the future.

Key Action Statement 5A

Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) OR failure to improve (lack of reduction in all presenting signs/symptoms) within 72 hours of initial management (Evidence Quality: C; Recommendation).

KAS Profile 5A

Aggregate evidence quality: C; observational studies

Benefits	Identification of patients who may have been misdiagnosed, those at risk of complications, and those who require a change in management.
Harm	Delay of up to 72 hours in changing therapy if patient fails to improve.
Cost	Additional provider and caregiver time and resources.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Use of 72 hours to assess progress may result in excessive classification as treatment failures if premature; emphasis on importance of worsening illness in defining treatment failures.
Role of patient preferences	Caregivers determine whether the severity of the patient's illness justifies the report to clinician of the patient's worsening or failure to improve.
Intentional vagueness	None.
Exclusions	Patients with severe illness, poor general health, complicated sinusitis, immune deficiency, previous sinus surgery, or coexisting bacterial illness.
Strength	Recommendation.

The purpose of this key action statement is to ensure that patients with acute bacterial sinusitis who fail to improve symptomatically after initial management are reassessed to be certain that they have been correctly diagnosed and to consider initiation of alternate therapy to hasten resolution of symptoms and avoid complications. "Worsening" is defined as progression of presenting signs or symptoms of acute bacterial sinusitis or onset of new signs or symptoms. "Failure to improve" is lack of reduction in presenting signs or symptoms of acute

bacterial sinusitis by 72 hours after diagnosis and initial management; patients with persistent but improving symptoms do not meet this definition.

The rationale for using 72 hours as the time to assess treatment failure for acute bacterial sinusitis is based on clinical outcomes in RCTs. Wald et al⁴¹ found that 18 of 35 patients (51%) receiving placebo demonstrated symptomatic improvement within 3 days of initiation of treatment; only an additional 3 patients receiving placebo (9%) improved between days 3 and 10. In the same study, 48 of 58 patients

(83%) receiving antibiotics were cured or improved within 3 days; at 10 days, the overall rate of improvement was 79%, suggesting that no additional patients improved between days 3 and 10. In a more recent study, 17 of 19 children who ultimately failed initial therapy with either antibiotic or placebo demonstrated failure to improve within 72 hours.⁴ Although Garbutt et al⁴² did not report the percentage of patients who improved by day 3, they did demonstrate that the majority of improvement in symptoms occurred within

the first 3 days of study entry whether they received active treatment or placebo.

Reporting of either worsening or failure to improve implies a shared responsibility between clinician and caregiver. Although the clinician should educate the caregiver regarding the anticipated reduction in symptoms within 3 days, it is incumbent on the caregiver to appropriately notify the clinician of concerns regarding worsening or failure to improve. Clinicians should emphasize the importance of reassessing those children whose symptoms are worsening whether or not antibiotic therapy was prescribed. Reassessment may be indicated before the 72-hour

process by which such reporting occurs should be discussed at the time the initial management strategy is determined.

Key Action Statement 5B

If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve in 72 hours, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic OR initiate antibiotic treatment of the child initially managed with observation (Evidence Quality: D; Option based on expert opinion, case reports, and reasoning from first principles).

KAS Profile 5B

Aggregate evidence quality: D; expert opinion and reasoning from first principles.

Benefit	Prevention of complications, administration of effective therapy.
Harm	Adverse effects of secondary antibiotic therapy.
Cost	Direct cost of medications, often substantial for second-line agents.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Clinician must determine whether cost and adverse effects associated with change in antibiotic is justified given the severity of illness.
Role of patient preferences	Limited in patients whose symptoms are severe or worsening, but caregivers of mildly affected children who are failing to improve may reasonably defer change in antibiotic.
Intentional vagueness	None.
Exclusions	None.
Strength	Option.

mark if the patient is substantially worse, because it may indicate the development of complications or a need for parenteral therapy. Conversely, in some cases, caregivers may think that symptoms are not severe enough to justify a change to an antibiotic with a less desirable safety profile or even the time, effort, and resources required for reassessment. Accordingly, the circumstances under which caregivers report back to the clinician and the

The purpose of this key action statement is to ensure optimal antimicrobial treatment of children with acute bacterial sinusitis whose symptoms worsen or fail to respond to the initial intervention to prevent complications and reduce symptom severity and duration (see Table 4).

Clinicians who are notified by a caregiver that a child's symptoms are worsening or failing to improve should confirm that the clinical diagnosis of acute bacterial sinusitis

corresponds to the patient's pattern of illness, as defined in Key Action Statement 1. If caregivers report worsening of symptoms at any time in a patient for whom observation was the initial intervention, the clinician should begin treatment as discussed in Key Action Statement 4. For patients whose symptoms are mild and who have failed to improve but have not worsened, initiation of antimicrobial agents or continued observation (for up to 3 days) is reasonable.

If caregivers report worsening of symptoms after 3 days in a patient initially treated with antimicrobial agents, current signs and symptoms should be reviewed to determine whether acute bacterial sinusitis is still the best diagnosis. If sinusitis is still the best diagnosis, infection with drug-resistant bacteria is probable, and an alternate antimicrobial agent may be administered. Face-to-face reevaluation of the patient is desirable. Once the decision is made to change medications, the clinician should consider the limitations of the initial antibiotic coverage, the anticipated susceptibility of residual bacterial pathogens, and the ability of antibiotics to adequately penetrate the site of infection. Cultures of sinus or nasopharyngeal secretions in patients with initial antibiotic failure have identified a large percentage of bacteria with resistance to the original antibiotic.^{71,72} Furthermore, multidrug-resistant *S pneumoniae* and β -lactamase-positive *H influenzae* and *M catarrhalis* are more commonly isolated after previous antibiotic exposure.^{73–78} Unfortunately, there are no studies in children that have investigated the microbiology of treatment failure in acute bacterial sinusitis or cure rates using second-line antimicrobial agents. As a result, the likelihood of adequate antibiotic coverage for resistant organisms must be

addressed by extrapolations from studies of acute otitis media in children and sinusitis in adults and by using the results of data generated in vitro. A general guide to management of the child who worsens in 72 hours is shown in Table 4.

NO RECOMMENDATION

Adjuvant Therapy

Potential adjuvant therapy for acute sinusitis might include intranasal corticosteroids, saline nasal irrigation or lavage, topical or oral decongestants, mucolytics, and topical or oral antihistamines. A recent Cochrane review on decongestants, antihistamines, and nasal irrigation for acute sinusitis in children found no appropriately designed studies to determine the effectiveness of these interventions.⁷⁹

Intranasal Steroids

The rationale for the use of intranasal corticosteroids in acute bacterial sinusitis is that an antiinflammatory agent may reduce the swelling around the sinus ostia and encourage drainage, thereby hastening recovery. However, there are limited data on how much inflammation is present, whether the inflammation is responsive to steroids, and whether there are differences in responsivity according to age. Nonetheless, there are several RCTs in adolescents and adults, most of which do show significant differences compared with placebo or active comparator that favor intranasal steroids in the reduction of symptoms and the patient's global assessment of overall improvement.^{80–85} Several studies in adults with acute bacterial sinusitis provide data supporting the use of intranasal steroids as either monotherapy or adjuvant therapy to antibiotics.^{81,86} Only one study did not show efficacy.⁸⁵

There have been 2 trials of intranasal steroids performed exclusively in

children: one comparing intranasal corticosteroids versus an oral decongestant⁸⁷ and the other comparing intranasal corticosteroids with placebo.⁸⁸ These studies showed a greater rate of complete resolution⁸⁷ or greater reduction in symptoms in patients receiving the steroid preparation, although the effects were modest.⁸⁸ It is important to note that nearly all of these studies (both those reported in children and adults) suffered from substantial methodologic problems. Examples of these methodologic problems are as follows: (1) variable inclusion criteria for sinusitis, (2) mixed populations of allergic and nonallergic subjects, and (3) different outcome criteria. All of these factors make deriving a clear conclusion difficult. Furthermore, the lack of stringent criteria in selecting the subject population increases the chance that the subjects had viral URIs or even persistent allergies rather than acute bacterial sinusitis.

The intranasal steroids studied to date include budesonide, flunisolide, fluticasone, and mometasone. There is no reason to believe that one steroid would be more effective than another, provided equivalent doses are used.

Potential harm in using nasal steroids in children with acute sinusitis includes the increased cost of therapy, difficulty in effectively administering nasal sprays in young children, nasal irritation and epistaxis, and potential systemic adverse effects of steroid use. Fortunately, no clinically significant steroid adverse effects have been discovered in studies in children.^{89–96}

Saline Irrigation

Saline nasal irrigation or lavage (not saline nasal spray) has been used to remove debris from the nasal cavity and temporarily reduce tissue edema (hypertonic saline) to promote drainage from the sinuses. There have been

very few RCTs using saline nasal irrigation or lavage in acute sinusitis, and these have had mixed results.^{97,98} The 1 study in children showed greater improvement in nasal airflow and quality of life as well as a better rate of improvement in total symptom score when compared with placebo in patients treated with antibiotics and decongestants.⁹⁸ There are 2 Cochrane reviews published on the use of saline nasal irrigation in acute sinusitis in adults that showed variable results. One review published in 2007⁹⁹ concluded that it is a beneficial adjunct, but the other, published in 2010,¹⁰⁰ concluded that most trials were too small or contained too high a risk of bias to be confident about benefits.

Nasal Decongestants, Mucolytics, and Antihistamines

Data are insufficient to make any recommendations about the use of oral or topical nasal decongestants, mucolytics, or oral or nasal spray antihistamines as adjuvant therapy for acute bacterial sinusitis in children.⁷⁹ It is the opinion of the expert panel that antihistamines should not be used for the primary indication of acute bacterial sinusitis in any child, although such therapy might be helpful in reducing typical allergic symptoms in patients with atopy who also have acute sinusitis.

OTHER RELATED CONDITIONS

Recurrence of Acute Bacterial Sinusitis

Recurrent acute bacterial sinusitis (RABS) is an uncommon occurrence in healthy children and must be distinguished from recurrent URIs, exacerbations of allergic rhinitis, and chronic sinusitis. The former is defined by episodes of bacterial infection of the paranasal sinuses lasting fewer than 30 days and separated by intervals of

TABLE 3 Parent Information Regarding Initial Management of Acute Bacterial Sinusitis

How common are sinus infections in children?	Thick, colored, or cloudy mucus from your child's nose frequently occurs with a common cold or viral infection and does not by itself mean your child has sinusitis. In fact, fewer than 1 in 15 children get a true bacterial sinus infection during or after a common cold.
How can I tell if my child has bacterial sinusitis or simply a common cold?	Most colds have a runny nose with mucus that typically starts out clear, becomes cloudy or colored, and improves by about 10 d. Some colds will also include fever (temperature $>38^{\circ}\text{C}$ [100.4°F]) for 1 to 2 days. In contrast, acute bacterial sinusitis is likely when the pattern of illness is persistent, severe, or worsening. 1. <i>Persistent</i> sinusitis is the most common type, defined as runny nose (of any quality), daytime cough (which may be worse at night), or both for at least 10 days without improvement. 2. <i>Severe</i> sinusitis is present when fever (temperature $\geq 39^{\circ}\text{C}$ [102.2°F]) lasts for at least 3 days in a row and is accompanied by nasal mucus that is thick, colored, or cloudy. 3. <i>Worsening</i> sinusitis starts with a viral cold, which begins to improve but then worsens when bacteria take over and cause new-onset fever (temperature $\geq 38^{\circ}\text{C}$ [100.4°F]) or a substantial increase in daytime cough or runny nose.
If my child has sinusitis, should he or she take an antibiotic?	Children with <i>persistent</i> sinusitis may be managed with either an antibiotic or with an additional brief period of observation, allowing the child up to another 3 days to fight the infection and improve on his or her own. The choice to treat or observe should be discussed with your doctor and may be based on your child's quality of life and how much of a problem the sinusitis is causing. In contrast, all children diagnosed with <i>severe</i> or <i>worsening</i> sinusitis should start antibiotic treatment to help them recover faster and more often.
Why not give all children with acute bacterial sinusitis an immediate antibiotic?	Some episodes of <i>persistent</i> sinusitis include relatively mild symptoms that may improve on their own in a few days. In addition, antibiotics can have adverse effects, which may include vomiting, diarrhea, upset stomach, skin rash, allergic reactions, yeast infections, and development of resistant bacteria (that make future infections more difficult to treat).

at least 10 days during which the patient is asymptomatic. Some experts require at least 4 episodes in a calendar year to fulfill the criteria for this condition. Chronic sinusitis is manifest as 90 or more uninterrupted days of respiratory symptoms, such as cough, nasal discharge, or nasal obstruction. Children with RABS should be evaluated for underlying allergies, particularly allergic rhinitis; quantitative and functional immunologic defect(s),

chiefly immunoglobulin A and immunoglobulin G deficiency; cystic fibrosis; gastroesophageal reflux disease; or dysmotile cilia syndrome.¹⁰¹ Anatomic abnormalities obstructing one or more sinus ostia may be present. These include septal deviation, nasal polyps, or concha bullosa (pneumatization of the middle turbinate); atypical ethmoid cells with compromised drainage; a lateralized middle turbinate; and intrinsic ostiomeatal anomalies.¹⁰²

Contrast-enhanced CT, MRI, or endoscopy or all 3 should be performed for detection of obstructive conditions, particularly in children with genetic or acquired craniofacial abnormalities.

The microbiology of RABS is similar to that of isolated episodes of acute bacterial sinusitis and warrants the same treatment.⁷² It should be recognized that closely spaced sequential courses of antimicrobial therapy may foster the emergence of antibiotic-resistant bacterial species as the causative agent in recurrent episodes. There are no systematically evaluated options for prevention of RABS in children. In general, the use of prolonged prophylactic antimicrobial therapy should be avoided and is not usually recommended for children with recurrent acute otitis media. However, when there are no recognizable predisposing conditions to remedy in children with RABS, prophylactic antimicrobial agents may be used for several months during the respiratory season. Enthusiasm for this strategy is tempered by concerns regarding the encouragement of bacterial resistance. Accordingly, prophylaxis should only be considered in carefully selected children whose infections have been thoroughly documented.

Influenza vaccine should be administered annually, and PCV-13 should be administered at the recommended ages for all children, including those with RABS. Intranasal steroids and nonsedating antihistamines can be helpful for children with allergic rhinitis, as can antireflux medications for those with gastroesophageal reflux disease. Children with anatomic abnormalities may require endoscopic surgery for removal of or reduction in ostiomeatal obstruction.

The pathogenesis of chronic sinusitis is poorly understood and appears to be multifactorial; however, many of the conditions associated with RABS

TABLE 4 Management of Worsening or Lack of Improvement at 72 Hours

Initial Management	Worse in 72 Hours	Lack of Improvement in 72 Hours
Observation	Initiate amoxicillin with or without clavulanate	Additional observation or initiate antibiotic based on shared decision-making
Amoxicillin	High-dose amoxicillin-clavulanate	Additional observation or high-dose amoxicillin-clavulanate based on shared decision-making
High-dose amoxicillin-clavulanate	Clindamycin ^a and cefixime OR linezolid and cefixime OR levofloxacin	Continued high-dose amoxicillin-clavulanate OR clindamycin ^a and cefixime OR linezolid and cefixime OR levofloxacin

^a Clindamycin is recommended to cover penicillin-resistant *S pneumoniae*. Some communities have high levels of clindamycin-resistant *S pneumoniae*. In these communities, linezolid is preferred.

have also been implicated in chronic sinusitis, and it is clear that there is an overlap between the 2 syndromes.^{101,102} In some cases, there may be episodes of acute bacterial sinusitis superimposed on a chronic sinusitis, warranting antimicrobial therapy to hasten resolution of the acute infection.

Complications of Acute Bacterial Sinusitis

Complications of acute bacterial sinusitis should be diagnosed when the patient develops signs or symptoms of orbital and/or central nervous system (intracranial) involvement. Rarely, complicated acute bacterial sinusitis can result in permanent blindness, other neurologic sequelae, or death if not treated promptly and appropriately. Orbital complications have been classified by Chandler et al.³² Intracranial complications include epidural or subdural abscess, brain abscess, venous thrombosis, and meningitis.

Periorbital and intraorbital inflammation and infection are the most common complications of acute sinusitis and most often are secondary to acute ethmoiditis in otherwise healthy young children. These disorders are commonly classified in relation to the orbital septum; periorbital or preseptal inflammation involves only the eyelid, whereas postseptal (intraorbital) inflammation involves structures of the orbit. Mild cases of preseptal cellulitis (eyelid <50% closed) may be treated on an outpatient basis with appropriate

oral antibiotic therapy (high-dose amoxicillin-clavulanate for comprehensive coverage) for acute bacterial sinusitis and daily follow-up until definite improvement is noted. If the patient does not improve within 24 to 48 hours or if the infection is progressive, it is appropriate to admit the patient to the hospital for antimicrobial therapy. Similarly, if proptosis, impaired visual acuity, or impaired and/or painful extraocular mobility is present on examination, the patient should be hospitalized, and a contrast-enhanced CT should be performed. Consultation with an otolaryngologist, an ophthalmologist, and an infectious disease expert is appropriate for guidance regarding the need for surgical intervention and the selection of antimicrobial agents.

Intracranial complications are most frequently encountered in previously healthy adolescent males with frontal sinusitis.^{33,34} In patients with altered mental status, severe headache, or Pott's puffy tumor (osteomyelitis of the frontal bone), neurosurgical consultation should be obtained. A contrast-enhanced CT scan (preferably coronal thin cut) of the head, orbits, and sinuses is essential to confirm intracranial or intraorbital suppurative complications; in such cases, intravenous antibiotics should be started immediately. Alternatively, an MRI may also be desirable in some cases of intracranial abnormality. Appropriate antimicrobial therapy for intraorbital complications include vancomycin (to cover possible methicillin-resistant

S aureus or penicillin-resistant *S pneumoniae*) and either ceftriaxone, ampicillin-sulbactam, or piperacillin-tazobactam.¹⁰³ Given the polymicrobial nature of sinogenic abscesses, coverage for anaerobes (ie, metronidazole) should also be considered for intra-orbital complications and should be started in all cases of intracranial complications if ceftriaxone is prescribed.

Patients with small orbital, subperiosteal, or epidural abscesses and minimal ocular and neurologic abnormalities may be managed with intravenous antibiotic treatment for 24 to 48 hours while performing frequent visual and mental status checks.¹⁰⁴ In patients who develop progressive signs and symptoms, such as impaired visual acuity, ophthalmoplegia, elevated intraocular pressure (>20 mm), severe proptosis (>5 mm), altered mental status, headache, or vomiting, as well as those who fail to improve within 24 to 48 hours while receiving antibiotics, prompt surgical intervention and drainage of the abscess should be undertaken.¹⁰⁴ Antibiotics can be tailored to the results of culture and sensitivity studies when they become available.

AREAS FOR FUTURE RESEARCH

Since the publication of the original guideline in 2001, only a small number of high-quality studies of the diagnosis and treatment of acute bacterial sinusitis in children have been published.⁵ Ironically, the number of published guidelines on the topic (5) exceeds the number of prospective,

placebo-controlled clinical trials of either antibiotics or ancillary treatments of acute bacterial sinusitis. Thus, as was the case in 2001, there are scant data on which to base recommendations. Accordingly, areas for future research include the following:

Etiology

1. Reexamine the microbiology of acute sinusitis in children in the postpneumococcal conjugate vaccine era and determine the value of using newer polymerase chain reaction–based respiratory testing to document viral, bacterial, and polymicrobial disease.
2. Correlate cultures obtained from the middle meatus of the maxillary sinus of infected children with cultures obtained from the maxillary sinus by puncture of the antrum.
3. Conduct more and larger studies to more clearly define and correlate the clinical findings with the various available diagnostic criteria of acute bacterial sinusitis (eg, sinus aspiration and treatment outcome).
4. Develop noninvasive strategies to accurately diagnose acute bacterial sinusitis in children.
5. Develop imaging technology that differentiates bacterial infection from viral infection or allergic inflammation, preferably without radiation.

Treatment

1. Determine the optimal duration of antimicrobial therapy for children with acute bacterial sinusitis.
2. Evaluate a “wait-and-see prescription” strategy for children with

persistent symptom presentation of acute sinusitis.

3. Determine the optimal antimicrobial agent for children with acute bacterial sinusitis, balancing the incentives of choosing narrow-spectrum agents against the known microbiology of the disease and resistance patterns of likely pathogens.
4. Determine the causes and treatment of subacute, recurrent acute, and chronic bacterial sinusitis.
5. Determine the efficacy of prophylaxis with antimicrobial agents to prevent RABS.
6. Determine the effects of bacterial resistance among *S pneumoniae*, *H influenzae*, and *M catarrhalis* on outcome of treatment with antibiotics by the performance of randomized, double-blind, placebo-controlled studies in well-defined populations of patients.
7. Determine the role of adjuvant therapies (antihistamines, nasal corticosteroids, mucolytics, decongestants, nasal irrigation, etc) in patients with acute bacterial sinusitis by the performance of prospective, randomized clinical trials.
8. Determine whether early treatment of acute bacterial sinusitis prevents orbital or central nervous system complications.
9. Determine the role of complementary and alternative medicine strategies in patients with acute bacterial sinusitis by performing systematic, prospective, randomized clinical trials.

10. Develop new bacterial and viral vaccines to reduce the incidence of acute bacterial sinusitis.

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TECHNICAL REPORT

Evidence for the Diagnosis and Treatment of Acute Uncomplicated Sinusitis in Children: A Systematic Review

abstract

FREE

In 2001, the American Academy of Pediatrics published clinical practice guidelines for the management of acute bacterial sinusitis (ABS) in children. The technical report accompanying those guidelines included 21 studies that assessed the diagnosis and management of ABS in children. This update to that report incorporates studies of pediatric ABS that have been performed since 2001. Overall, 17 randomized controlled trials of the treatment of sinusitis in children were identified and analyzed. Four randomized, double-blind, placebo-controlled trials of antimicrobial therapy have been published. The results of these studies varied, likely due to differences in inclusion and exclusion criteria. Because of this heterogeneity, formal meta-analyses were not performed. However, qualitative analysis of these studies suggests that children with greater severity of illness at presentation are more likely to benefit from antimicrobial therapy. An additional 5 trials compared different antimicrobial therapies but did not include placebo groups. Six trials assessed a variety of ancillary treatments for ABS in children, and 3 focused on subacute sinusitis. Although the number of pediatric trials has increased since 2001, there are still limited data to guide the diagnosis and management of ABS in children. Diagnostic and treatment guidelines focusing on severity of illness at the time of presentation have the potential to identify those children most likely to benefit from antimicrobial therapy and at the same time minimize unnecessary use of antibiotics. *Pediatrics* 2013;132:e284–e296

INTRODUCTION

Acute bacterial sinusitis is reported as a complication of 5% to 10% of upper respiratory tract infections in children^{1,2} and is 1 of the more common indications for antibiotic use in the United States. In 2001, the American Academy of Pediatrics (AAP) published clinical practice guidelines for the management of sinusitis in children.³ The 2001 technical report that accompanied those guidelines included an analysis of 21 studies published from January 1966 through March 1999 which assessed the diagnosis and therapeutic management of acute sinusitis in children.⁴ These included 5 randomized controlled trials involving 255 children and 8 case series involving 418 children. The primary goal of the current analysis was to update the 2001

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KEY WORDS

acute bacterial sinusitis, antibiotics, ancillary treatment, diagnosis, systematic review

ABBREVIATIONS

AAP—American Academy of Pediatrics

CT—computed tomography

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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technical report by identifying and reviewing additional studies of pediatric acute sinusitis that have been performed in the last decade to aid the revision of the AAP practice guidelines.

This technical report revisits the same questions as the original report: (1) What is the efficacy of various types of antimicrobial therapy in children with acute sinusitis? (2) What is the efficacy of nonantimicrobial ancillary treatments in children with acute sinusitis? (3) What is the concordance of various clinical, laboratory, and radiographic findings in the diagnosis of acute sinusitis? In addition, the Subcommittee on Management of Sinusitis met before the initial literature search for the current report and raised additional questions:

1. What is the incidence of adverse events in the treatment of sinusitis?
2. Are there data to support the clinical definitions of acute, subacute, and recurrent acute sinusitis?
3. Are there data to recommend a specific duration of symptoms that distinguishes bacterial from viral sinusitis?
4. How have the epidemiology and bacteriology of acute sinusitis changed in the pneumococcal conjugate vaccine era?
5. Is there evidence to support antimicrobial prophylaxis in children with recurrent sinusitis?
6. What other guidelines for the management of acute sinusitis in children exist?

METHODS

Searches of PubMed were performed by using the same search term as in the 2001 report ("sinusitis"). All searches were limited to English language and human studies. Three separate searches were performed to

maximize retrieval of the most recent and highest-quality evidence for pediatric sinusitis. The first search limited results to all randomized controlled trials from 1966 to 2009, the second to all meta-analyses from 1966 to 2009, and the third to all pediatric studies (age limit <18 years) published since the last technical report (1999–2009). In addition, Web of Science was used to search for additional studies that cited the 2001 technical report and guidelines as well as citations of each double-blind, randomized controlled pediatric trial identified. The Cochrane Database of Systematic Reviews was also reviewed. Finally, ClinicalTrials.gov was searched to identify results of unpublished and ongoing studies. The Jadad scale (Table 1) was used to assess the quality of randomized trials included in this analysis.⁵ Additional literature updates using the same search strategies were performed in July 2010 and November 2012.

Whenever possible, data from randomized controlled trials (preferably placebo controlled) were used to answer the questions raised by the committee. When no such data were available, separate literature searches were performed.

TABLE 1 Criteria for Assessing Randomized Trials

Give 1 point for each of the following:
a. The study is described as randomized
b. The study is described as double-blind
c. There was a description of withdrawals and dropouts
Given 1 additional point if:
a. For randomized studies, the method of randomization was described and is appropriate
b. For double-blind studies, the method of blinding was described and is appropriate
Deduct 1 point if:
c. For randomized studies, the method of randomization was described and is inappropriate
d. For double-blind studies, the method of blinding was described and is inappropriate

Adapted from Jadad et al.⁵

RESULTS

In the initial search, 183 randomized trials were identified, 98 of which were published since 1998. Of these 98, a total of 62 were eliminated on the basis of titles indicating a focus on adults, chronic sinusitis, or post-surgical management. Inclusion criteria and results of the remaining 36 studies were reviewed. Seven studies included adolescents as young as 12 years, but they represented <2% of the study population, and no age-specific results were reported. Twenty-one additional studies included teenagers but did not report how many were included; average ages for these studies were in the third to fourth decade of life. The updated literature search in July 2010 identified 2 additional randomized controlled trials that focused on ancillary treatment of sinusitis in children. A final search performed in November 2012 did not identify any additional controlled trials.

Overall, 17 randomized studies of sinusitis in children were identified and included in the current analysis. The meta-analysis search identified 1 study that focused exclusively on children and 2 others that focused primarily on adults but also assessed and separately reported results of pediatric studies. A review of ClinicalTrials.gov identified 28 sinusitis studies including children aged <18 years, only 3 of which were limited exclusively to children. One of these (Wald et al⁶) has recently been published and is included in the analysis; the other 2 studies are not yet recruiting patients.

TREATMENT

Efficacy of Antimicrobial Therapy

Randomized Placebo-Controlled Trials

Four randomized, double-blind, placebo-controlled trials involving 392 children were identified (Table 2).^{6–9} An

additional study¹⁰ that was included in the previous technical report was excluded because it included patients with chronic and subacute sinusitis. The results of these 4 studies varied. Two studies favored treatment, and the other 2 found no significant difference in clinical cure between the treatment and control groups.

Clinical improvement in children receiving placebo ranged from 14% to 79% across the 4 studies, suggesting significant heterogeneity. The outcomes in the treatment groups were less varied, ranging from 50% to 81%. However, the efficacies of specific treatments are difficult to compare directly because the studies were performed over a 25-year period, during which a universal conjugate pneumococcal vaccination program was introduced and the prevalence of penicillin-resistant *Streptococcus pneumoniae* and β -lactamase-producing *Moraxella* and *Haemophilus* species increased.

The disparity in outcomes in the placebo groups is likely explained by the different methods used in each study. Notably, the inclusion criteria differed between each of the 4 studies. For instance, the minimal duration of symptoms required for entry into the study by Kristo et al⁹ was not specified and averaged between 8 and 9 days for the treatment and control groups, respectively. Furthermore, only 32% of subjects had symptoms lasting at least 10 days. Therefore, the results of this study are not generalizable to the AAP definition of sinusitis, which is 10 days of symptoms, and should not be considered in the revised guidelines. Inclusion criteria for persistent symptoms in the other 3 studies were similar. Each specified respiratory symptoms that persisted for at least 10 days but <30 days. Only the 1986 study by Wald et al⁷ required an abnormal radiograph for study entry.

Another study by Wald et al (in 2009)⁶ was the only trial to include a subgroup of children who met criteria for worsening (on or after day 6 with fever or increase in symptoms) or severe (temperature $\geq 102^{\circ}\text{F}$ with purulent discharge for at least 3 consecutive days) symptoms of sinusitis.

Exclusion criteria for each of these 3 studies had some similarities. Allergy to study drug, recent receipt of antibiotics, and concurrent bacterial infection requiring treatment were exclusion criteria in all of the studies. Complications of sinusitis were also listed as exclusion criteria, although the definitions of this factor differed between the studies. For instance, Garbutt et al⁸ excluded children with “fulminant sinusitis,” including children with fever $\geq 39^{\circ}\text{C}$ (102.2°F); this condition was a specific inclusion criterion for the severe group in the 2009 study by Wald et al.⁶ In addition, underlying medical conditions were used to exclude children, but the specific diagnoses differed in the 3 studies. Wald et al⁷ excluded children with a variety of underlying medical conditions, including history of asthma and allergic rhinitis. Garbutt et al⁸ only excluded children with cystic fibrosis; children with asthma and allergic rhinitis were included. Wald et al⁶ only excluded children with immunodeficiency or anatomic abnormality of the upper respiratory tract.

The 3 studies used similar randomization schemes: patients were stratified according to age group and clinical severity before randomization. However, the metrics of clinical severity differed. The 2 studies by Wald et al^{6,7} used a 10-point questionnaire (Table 3), and the study by Garbutt et al⁸ used the S5 score (Table 4), previously validated by the same author.¹¹ Although each of these 3 studies stratified patients according to clinical severity before randomization,

separate results stratified by severity are not reported. This information may be helpful in the identification of patients (on the basis of clinical grounds) who might benefit from antimicrobial therapy.

Another key methodologic difference is that the study by Wald et al (1986)⁷ did not use intention-to-treat analysis. Fifteen (14%) of 108 children were excluded because of lack of compliance or drug toxicity, which may have introduced bias.

Because of these significant differences in study design, formal meta-analyses were not performed. However, qualitative analysis of these results suggests that there may be certain clinical characteristics that identify patients who benefit from antimicrobial therapy.

Randomized Controlled Comparison Trials

In addition to the 4 placebo-controlled studies described previously, there have been other randomized studies of acute sinusitis in children comparing different antimicrobial treatment courses (Table 5).^{12–16} Three of these were included in the previous report, and 2 additional studies have been published since 1998. None of these studies demonstrated a clear advantage of 1 therapy over another, and rates of cure or improvement were well above 80%. Although these studies offer some insight into the relative efficacies of different treatments, they do not include a placebo group. This factor is important given that many of the children included in these studies may have improved spontaneously without any specific antimicrobial therapy. In addition, none of these studies was designed as noninferiority or equivalence studies and, therefore, may have been underpowered to detect true differences between competing treatments.

TABLE 2 Randomized, Placebo-Controlled Trials of Antimicrobial Treatment of Acute Sinusitis in Children

Variable	Wald et al ⁷	Garbutt et al ⁸	Kristo et al ⁹	Wald et al ⁶
Inclusion criteria	Nasal discharge of any quality and/or Cough Symptoms present for 10–30 d Age: 2–16 y Abnormal radiograph results	“Persistent upper respiratory symptoms” Symptoms present for 10–28 d Age: 1–18 y NA Allergy	Acute respiratory symptoms suggestive of sinusitis that were “not improving” Nasal discharge and obstruction, sneezing, cough Symptoms present <3 wk, no lower bound Age: 4–10 y Abnormal US Allergy	Persistent: nasal discharge of any quality and/or daytime cough persisting for >10 d without improvement Worsening: worsening on or after day 6 with fever or increase in symptoms Severe: temperature $\geq 102^{\circ}\text{F}$ with purulent nasal discharge for at least 3 consecutive days Symptoms present <30 d, lower bound per definitions above Age: 1–10 y NA Allergy
Exclusion criteria	Previous Rx within 3 d Underlying conditions (asthma, allergic rhinitis, CF, sickle cell anemia, congenital heart disease, immunodeficiency) Otitis media, pneumonia, GAS pharyngitis (throat/NP culture performed at study enrollment) Severe headache or periorbital swelling Normal radiograph of paranasal sinuses	Previous Rx within 2 wk CF only “Fulminant sinusitis” (fever $>39^{\circ}\text{C}$, facial swelling, facial pain) NA	Previous Rx within 4 wk Previous sinus surgery Current antimicrobial Rx “Complications of sinus disease” NA	Previous Rx within 15 d Underlying conditions (immunodeficiency or anatomic abnormality of upper respiratory tract) Concurrent bacterial infection Complication of sinusitis requiring hospitalization, IV antibiotics, or subspecialty evaluation. NA
Source of patients	Primary or secondary care patients at an academic children’s hospital	3 suburban primary care practices	1 private health care center	2 private practices, 1 hospital-based clinic
Randomization			Block randomization	Assigned to persistent or nonpersistent group then stratified by age: (<6 and ≥ 6 y) And clinical severity Then randomized
Metric for severity	Clinical severity score: <8 is mild and ≥ 8 is severe	Clinical severity score using S5 score	8 acute symptoms, rated 0–4	Same as Wald et al ⁷
Telephone follow-up	1, 2, 3, 5, and 7 d	3, 7, 10, 14, 21, 28, and 60 d	NA	1, 2, 3, 5, 7, 10, 20, and 30 d
Clinical visit	Day 10	Day 14	Day 14	Day 14
Primary outcome	Clinical outcome at 3 and 10 d	Change in sinus symptoms at day 14	% complete cure at 2 wk	Cure at day 14
Secondary outcomes	Not specified	Adverse events Relapse Change in functional status Parental satisfaction with treatment	Adverse effects Improvement without complications Days when analgesics, nasal decongestants or cough mixtures were given	Adverse events Proportion with treatment failure
N placebo	35	55	41	28
N treatment group	30 amoxicillin (40 mg/kg per day) divided 3 times/d for 10 d 28 amoxicillin/clavulanate	58 amoxicillin (40 mg/kg per day) divided 3 times/d for 14 d 48 amoxicillin/clavulanate (45 mg/kg per day amoxicillin) divided 2 times/d for 14 d	41 cefuroxime 125 mg 2 times/d for 10 d	28 amoxicillin/clavulanate (90 mg/kg amoxicillin + 6.4 mg clavulanate) divided 2 times/d for 14 days
Adjuvant therapy	None were prescribed. Not formally studied	Prescription or over-the-counter symptomatic treatments allowed. Use recorded	Analgesics, nose drops, and cough mixtures allowed. Use recorded in diary	Use “discouraged”—not formally studied
Compliance	History and remaining medications at follow-up visit	Self-report at day 14	Residual drugs collected at day 14	History and remaining medications at follow-up visit

TABLE 2 Continued

Variable	Wald et al ⁷	Garbutt et al ⁸	Kristo et al ⁹	Wald et al ⁶
Adverse events	Children who developed rash and diarrhea were excluded from analysis	Assessed at day 14	Assessed at day 14	Assessed at day 14
Loss to follow-up	15 children excluded because of adverse events (8) and noncompliance (7)	None (typographic error in original manuscript)	3 children (2 placebo, 1 treatment) lost to follow-up	6 lost to follow-up in treatment group
Primary outcome	Cure at 10 d: Amoxicillin: 20/30 (67%); Amoxicillin/clavulanate: 18/28 (64%); Placebo: 15/35 (43%) Total: Antibiotic: 38/58; Placebo: 15/35 (66% vs 43%; $P < .05$) Failure at 10 d: Amoxicillin: 5/30; Amoxicillin/clavulanate: 7/28; Placebo: 14/35 Total: Antibiotic: 12/58; Placebo: 15/35 (21% vs 43%; $P < .05$)	Improvement at 14 d: Amoxicillin: 79% (46/58); Amoxicillin/clavulanate: 81% (39/48); Placebo: 79% (43/55)	Cure at 14 d: 22/35 in experimental group vs 21/37 in placebo (63% vs 57%; $P = .64$)	Cure at 14 d: 14/28 in experimental group vs 4/28 in placebo (50% vs 14%; $P = .01$) Failure at 14 d: 4/28 in experimental group vs 19/28 in placebo (14% vs 68%; $P < .001$) If all subjects lost to follow-up were considered failures, therapy is still effective (35% vs 68%; $P = .032$)
Jadad score	3	5	4	4

CF, cystic fibrosis; GAS, group A streptococcal; IV, intravenous; NA, not applicable; NP, nasopharyngeal; Rx, prescription; US, ultrasonography.

In addition to these randomized comparator studies, Garbutt et al⁸ and Wald et al⁷ used amoxicillin and amoxicillin/clavulanic acid treatments arms in

their placebo-controlled studies. No significant differences between these 2 treatments were detected.

Adverse Events Associated With Antimicrobial Therapy

Randomized Placebo-Controlled Trials

Adverse effects of treatment were described in all 3 studies. In the first study by Wald et al,⁷ rash developed in 1 child in the amoxicillin group and 1 in the placebo group. Diarrhea, requiring cessation of therapy, developed in 6 children in the amoxicillin/clavulanic acid group and 1 child in the placebo group. In the study by Garbutt et al,⁸ one-half of all study participants reported an adverse effect; these events were equally distributed across the

study groups. Diarrhea was reported by 20% to 22% of participants ($P = .97$ between the 3 groups). The only reported adverse effect that reached statistical significance was abdominal pain, which occurred in 29% of children in the amoxicillin group but only 15% and 9% of children in the amoxicillin/clavulanate and placebo groups, respectively ($P = .02$). In the most recent study by Wald et al,⁶ 44% of children in the experimental group experienced an adverse event compared with 14% in the control group ($P = .014$). The incidences of specific adverse events were not described, but diarrhea was reportedly the most common. Although efficacy data from the study by Kristo et al⁹ should not be considered in the guidelines, data can be used to compare adverse events associated with antimicrobial therapy compared with placebo. In this study, 3 children developed self-limited diarrhea (1 in the cefuroxime group and 2 in the placebo group).

Randomized Controlled Comparison Trials

Adverse events were reported in 4 of these studies.^{12,14–16} The incidence of

TABLE 3 Scale Used in Studies by Wald et al^{6,7}

Symptoms or Signs	Points
Abnormal nasal or postnasal discharge	
Minimal	1
Severe	2
Nasal congestion	1
Cough	2
Malodorous breath	1
Facial tenderness	3
Erythematous nasal mucosa	1
Fever	
$<38.5^{\circ}\text{C}$	1
$\geq 38.5^{\circ}\text{C}$	2
Headache (retro-orbital)	
Severe	3
Mild	1

Interpretation: <8 = mild, ≥ 8 = severe.

TABLE 4 Scale Used by Garbutt et al¹¹

Symptom	Points			
	1	2	3	0
Blocked up or stuffy nose	Small	Medium	Large	Not a problem or do not know
Headaches or face pain	Small	Medium	Large	Not a problem or do not know
Coughing during the day	Small	Medium	Large	Not a problem or do not know
Coughing at night	Small	Medium	Large	Not a problem or do not know
Color of child's mucus			Yellow or green	None or clear

S5 score is obtained by averaging the scores for each symptom. In the clinical trial,⁸ children were stratified into 2 groups before randomization: S5 score <2 or S5 score ≥ 2 .

TABLE 5 Randomized Controlled Trials Comparing Different Antimicrobial Treatments for Acute Sinusitis

Author (Year)	Age (y)	Antimicrobial Agents	Duration	N	Cured (%)	Improved (%)	Failed (%)	Relapsed (%)	Recurred (%)	Jadad Score
Poachanukoon and Kitcharoensakkul (2008) ¹²	1–15	Amoxicillin-clavulanate (80–90 mg/kg per day)	14 d	72	ND	85	ND	11	6	3
Simon (1999) ¹³	0.5–17	Cefditoren (4–6 mg/kg) 2 times/d	14 d	66	ND	79	ND	9	3	1
		Erythromycin (40 mg/kg per day)	14 d	50	96	ND	4	ND	10	
		Ceftibuten (9 mg/kg per day)	10 d	50	92	ND	8	ND	12	
		Ceftibuten (9 mg/kg per day)	15 d	50	92	ND	8	ND	8	
		Ceftibuten (9 mg/kg per day)	20 d	50	100	ND	0	ND	8	
Ficnar et al (1997) ¹⁴	0.5–12	Azithromycin (10 mg/kg per day)	3 d	27	96	ND	0	4	ND	1
		Azithromycin (10 mg/kg on day 1, then 5 mg/kg on days 2–5)	5 d	18	100	ND	0	0	ND	
Careddu et al (1993) ¹⁵	2–14	Brodinoprim (10 mg/kg on day 1, then 5 mg/kg per day)	8 d	25	96	ND	4	ND	ND	1
		Amoxicillin-clavulanate (50 mg/kg per day)	NS	27	85	ND	15	ND	ND	
Wald et al (1984) ¹⁶	1–16	Amoxicillin (40 mg/kg per day)	10 d	27	81	4	11	4	4	3
		Cefaclor (40 mg/kg per day)	10 d	23	78	9	4	11	17	

ND, not determined; NS, not specified.

adverse events did not differ between study groups for 3 of these studies. Poachanukoon and Kitcharoensakkul¹² reported a higher rate of diarrhea (18.1%) in children receiving amoxicillin/clavulanate compared with those receiving cefditoren (4.5% [$P = .02$]). However, diarrhea was self-limited and did not require termination of medication or study withdrawal.

ANCILLARY TREATMENTS

Six randomized-controlled trials have assessed a variety of ancillary treatments for acute sinusitis (Table 6)^{17–20} and are summarized here.

Steroids

The 2001 technical report described 1 study that assessed the efficacy of intranasal steroids in children.¹⁷ In that study, 89 children received amoxicillin/clavulanate (40 mg/kg per day) and were randomized to receive either budesonide nasal spray ($n = 43$) or placebo ($n = 46$) for 3 weeks. Although no difference in symptom improvement was noted between the groups at the end of therapy (3 weeks), children in the budesonide group had improved cough and nasal discharge at 2 weeks,

whereas children in the placebo group did not, suggesting that corticosteroids may lead to more rapid resolution of symptoms. Since then, there has been 1 other randomized controlled trial in children studying the efficacy of intranasal budesonide.¹⁸ In this study, 52 children (mean age: 8 years; age range: 6–16 years) with acute maxillary sinusitis received cefaclor (40 mg/kg) for 10 days with either pseudoephedrine (2×30 mg daily) or intranasal budesonide (2×100 µg daily) for 10 days. There was no placebo group. Children with underlying allergy were excluded. Children in the budesonide group had statistically significantly better resolution of headache, cough, nasal stuffiness, and nasal drainage. There were no adverse events reported. However, these authors defined acute sinusitis as an infection that could take up to 12 weeks for complete resolution, and the results may therefore not be generalizable to AAP guidelines.

Decongestant-Antihistamine

No randomized controlled studies have been performed since a study cited in the 2001 report.¹⁹ All children in that

study received 14 days of amoxicillin (37.5–50 mg/kg per day, divided 3 times per day). They were then randomized to receive either placebo or the combination of oxymetazoline nasal spray and an oral decongestant-antihistamine. Both groups had marked clinical improvement in symptoms 3 days into treatment. In addition, there were no significant differences in clinical or radiographic findings between the 2 groups at the end of treatment.

Nasal Spray

One randomized controlled trial compared the use of 14 days of treatment with Ems mineral salts versus xylo-metazoline (0.05% solution) nasal spray in children with acute sinusitis.²⁰ There was no placebo group, and antibiotic use was not permitted. The primary outcome was mucosal inflammation (rubescence, swelling, and discharge) at baseline, day 7, and day 14. There were no significant differences between the 2 groups at day 14. However, at day 7, the mineral salt group had less nasal discharge than the xylometazoline group ($P = .0163$), suggesting that the spray may lead to more

TABLE 6 Randomized Controlled Trials of Ancillary Therapies for Acute Sinusitis

Author (Year)	Age (y)	Inclusion Criteria	Primary Therapy	LOT	Other Treatments	N	Main Outcome	Jadad Score
Barlan et al (1997) ¹⁷	1–15	2 major, or 1 major and 2 minor criteria. Duration >7 d; Major criteria: purulent nasal discharge, purulent pharyngeal drainage, cough; Minor criteria: periorbital edema, facial pain, tooth pain, earache, sore throat, wheeze, headache, foul breath, fever	Intranasal budesonide (50 µg each nostril) 2 times/day; Intranasal placebo bid	21 21	All received amoxicillin/clavulanate (40 mg/kg per day)	43 46	No difference in cough or nasal discharge scores at weeks 1 or 3. Budesonide scores statistically lower (less symptomatic) at week 2 for both outcomes	2
Yilmaz et al (2000) ¹⁸	6–16	Specific symptoms not specified Duration: infection that could take up to 12 wk to resolve	Intranasal budesonide (2 × 100 µg) Oral pseudoephedrine (2 × 30 mg)	10 10	All received cefaclor (40 mg/kg per day)	26 26	Budesonide group statistically better improvement in headache, cough, nasal stuffiness, and nasal drainage at day 10	1
McCormick et al (1996) ¹⁹	1–18	8–29 d of sinusitis symptoms	Oxymetazoline nasal spray (0.05%) plus syrup with decongestant-antihistamine Placebo nasal spray and syrup	14 14	All children received amoxicillin by age/weight: 10–12 kg, 150 mg tid; 12.1–15 kg, 200 mg tid; >15 kg, 250 mg tid Teenagers: 40 mg/kg per day (maximum: 500 tid)	34 34	No difference between groups in mean symptom score at enrollment, day 3, or day 14	4
Michel et al (2005) ²⁰	2–6	“Definition give[n] by the AAP”	Intranasal isotonic Ems mineral salts Intranasal xylometazoline (0.05%)	14 14	No additional treatment (including antibiotics) allowed	66 ^a	No difference in symptoms at day 14. Ems group had statistically significant less inflammation at day 7	2
Wang et al (2009) ²¹	3–12	(1) URI with purulent nasal discharge and/or cough >7 d (2) Abnormal findings of 1 or both maxillary sinuses by Water's projection	Standard therapy plus normal saline nasal irrigation, 15–20 mL per nostril 1–3 times/day Standard therapy alone	21 21	“Standard therapy” defined as systemic antibiotics, mucolytics, and nasal decongestants	30 39	Saline group had better scores for daytime rhinorrhea and nighttime nasal congestion. No statistically significant differences in quality of life score, nasal smear, or Water's projection	1
Unuvar et al (2010) ²²	3–12	(1) 10–30 d of URTI symptoms (2) Presence of severe symptoms of rhinosinusitis	Erdosteine syrup (5–8 mg/kg/day orally divided bid) Placebo	14 14	None	49 43	No significant difference in clinical improvement at 14 d between the 2 groups	4

bid, 2 times per day; LOT, length of therapy; tid, 3 times per day; URTI, upper respiratory tract infection.

^a Sixty-six patients in trial; numbers in each treatment arm not specified.

rapid resolution of symptoms. Wang et al²¹ randomized 69 children to receive standard therapy (systemic antibiotics, mucolytic agents, and nasal decongestants) or standard therapy plus nasal irrigation (15–20 mL of normal saline administered via syringe to each nostril 1–3 times per day). Outcomes included a daily nasal symptom score (summarized weekly), pediatric rhinoconjunctivitis quality of

life questionnaire (at baseline and 3 weeks), weekly nasal peak expiratory flow rate, weekly nasal smear, and Water's projection (baseline and 3 weeks). The irrigation group had significantly better symptom scores for daytime (but not nighttime) rhinorrhea at weeks 1, 2, and 3 and nighttime (but not daytime) nasal congestion at weeks 1, 2, and 3. Children in the irrigation group also had better nasal

peak expiratory flow rates and slightly better quality of life scores at 3 weeks. There were no statistically significant differences in nasal smear or Water's projections between the 2 groups after 3 weeks of treatment.

Mucolytic Agents

One randomized controlled trial assessed S5 scores in 49 children receiving the mucolytic erdosteine

compared with 43 children who received placebo.²² After 14 days of treatment, there was no significant difference in S5 scores between the 2 groups.

In addition to these studies, which were specifically designed to assess the efficacy of nonantimicrobial therapy, use of ancillary measures was measured and reported for 2 of the randomized trials of antimicrobial use. In the study by Garbutt et al,⁸ there were no significant differences in the overall use of ancillary therapies between the treatment and placebo groups (52% vs 48% vs 49%; $P = .92$). Although individual-level data were not presented, this finding makes it unlikely that unbalanced use of adjuvant therapies contributed to the study outcomes. Among individual therapies, only use of combination products was reported more frequently in 1 group (10% of amoxicillin/clavulanate vs 0% and 2% of amoxicillin and placebo, respectively; $P = .01$). In the study by Poachanukoon and Kitcharoensakul,¹² use of concomitant intranasal corticosteroids (52%) and oral decongestants (22%) was common but did not differ between the study groups.

DIAGNOSIS

Although sinus aspiration remains the gold standard for diagnosis of acute sinusitis, it is rarely practiced outside of the research setting. Furthermore, few recent studies have used aspiration as a criterion for study entry or used bacteriologic cure as an outcome. Despite these microbiologic limitations, evidence from the trials summarized previously can answer a slightly different question: which (if any) clinical, laboratory, and/or radiologic findings are able to discriminate between children who are likely to benefit from antimicrobial therapy and those who are not?

CLINICAL FINDINGS

Duration of Symptoms

The most commonly used diagnostic criterion for acute bacterial sinusitis is persistent or prolonged duration of symptoms for 10 to 14 days.²³ This criterion is based on the observation that most viral upper respiratory tract infections last 5 to 7 days.³ However, the study by Garbutt et al⁸ demonstrated that duration of symptoms alone was not sufficient to warrant antimicrobial therapy. A minimum of 10 days of symptoms was required for study entry, and all 3 groups had a mean duration of symptoms greater than 2 weeks (amoxicillin: 15.8 days; amoxicillin/clavulanate: 18.5 days; placebo: 15.4 days).

Signs and Symptoms

Purulent rhinorrhea, nasal congestion, and headache are other common findings used to diagnose sinusitis.²³ The various clinical trials used different combinations of these findings in their inclusion criteria. The 3 placebo-controlled studies limited to children with at least 10 days of symptoms also used clinical severity scores based on these signs and symptoms. Tables 2 and 3 stratify study participants before randomization. Because this stratification occurred before randomization, severity-specific results might help clarify which children are likely to benefit from antimicrobial therapy.

Imaging Studies

The 2001 guidelines recommended that radiologic studies should not be used to diagnose sinusitis in children 6 years or younger and that computed tomography (CT) should be considered only for children requiring surgery.³ Ultrasonography has also been suggested as a potential diagnostic tool for acute sinusitis. The 2001 technical

report cited 1 study that demonstrated good concordance between ultrasonographic findings and retrieval of fluid on sinus aspiration.²⁴ On the basis of that study, ultrasonographic findings (either mucosal thickening of ≥ 5 mm or fluid in at least 1 maxillary sinus) were used as entry criteria in the study by Kristo et al.⁹ In that study, children also underwent occipitontental radiography, and the film results were defined as positive for sinusitis if there was mucosal thickening of at least 4 mm, an air-fluid level, or total opacification of at least 1 maxillary sinus. Eighty-nine percent of children in the treatment group and 92% of those in the placebo group met this criterion, suggesting good concordance between plain films and ultrasonography. However, these findings were not predictive of which children would benefit from antimicrobial therapy. Radiographic studies were not used in the other 2 recent placebo-controlled studies.^{6,8}

Laboratory Studies

None of the studies required routine laboratory studies for study entry. Microbiologic samples were only obtained in 2 placebo-controlled studies and did not include direct sinus sampling. Wald et al⁷ used results of throat and nasopharyngeal cultures to exclude patients with group A streptococcal pharyngitis from their study. Kristo et al⁹ obtained nasopharyngeal cultures on all patients but only reported those with results positive for *Streptococcus pneumoniae* and *Haemophilus influenzae*, which occurred in 12.5% of study participants.

SUBACUTE SINUSITIS

Subacute sinusitis has been defined as infection that lasts between 30 and 90 days.³ Three small randomized

controlled trials assessing the efficacy of different treatment strategies for subacute sinusitis were identified (Table 7).^{25–27} None of these studies included a placebo group. One compared empirical amoxicillin/clavulanate with culture-based (from nasal mucosa) antimicrobial treatment.²⁵ Culture of nasal specimens was not performed on the children in the empirical antibiotic group. Five (18.5%) of 27 culture results in the experimental group were positive for amoxicillin/clavulanate-resistant organisms (1 *Pseudomonas* species, 2 resistant to *S pneumoniae*, and 2 anaerobic streptococci), and appropriate therapy was initiated. Nasal obstruction at day 14 was unchanged or worse for 9 children (36%) in the empirical arm but only 4 children (15%) in the culture-based arm ($P = .037$, per authors). Another study compared azithromycin versus amoxicillin/clavulanate.²⁶ The third compared amoxicillin, amoxicillin/clavulanic acid, trimethoprim/sulfamethoxazole, and no antimicrobial therapy.²⁷ In these 2 studies, no advantage was detected in

any treatment arm compared with others. However, the studies were small and were likely not powered to detect true differences.

CLINICAL QUESTIONS FOR WHICH HIGH-QUALITY DATA ARE LACKING

Definitions of Acute, Subacute, and Recurrent Acute Sinusitis

The definitions of acute, subacute, and recurrent acute sinusitis are outlined in the 2001 AAP guidelines.³ Although logical and based on the presumed pathogenesis of these distinct clinical entities, there are few clinical or laboratory data to confirm these definitions in children. One study of subacute sinusitis included 52 sinus aspirations of 40 children with subacute (30–120 days of symptoms) sinusitis and found similar pathogens as in acute sinusitis.²⁸ The definition of subacute sinusitis used in this study and in the study by Ng et al²⁶ were derived from an expert consensus panel.²⁹ The study by El-Hennawi et al²⁵ cites the 2001 AAP guidelines,

and the study by Dohlman et al²⁵ does not provide a reference for the study definition of subacute sinusitis.

Epidemiology of Sinusitis in the Pneumococcal Conjugate Vaccine Era

A separate literature search was performed to identify studies of sinusitis in the era of the pneumococcal conjugate vaccine. Although there are substantial data regarding the epidemiology of invasive pneumococcal disease and acute otitis media since implementation of pneumococcal immunization, no recent pediatric sinusitis studies that included microbiologic data were identified. Brook et al³⁰ compared culture results from sinuses of adults before and after introduction of the pneumococcal conjugate vaccine. There was a statistically significant decrease in the prevalence of *S pneumoniae* and a significant increase in the prevalence of *H influenzae*. In addition, there was a 12% decrease in penicillin resistance observed in pneumococcal

TABLE 7 Randomized Controlled Trials of Antimicrobial Therapy for Subacute Sinusitis

Author (Year)	Age (y)	Inclusion Criteria	Antimicrobial Agents	Length	Other Treatments	N	Better (%)	Worse or Same (%)	Jadad Score
El-Hennawi et al (2006) ²⁵	<2	Persistent nasal discharge and nasal obstruction for 30–90 d	Amoxicillin-clavulanate (40 mg/kg per day)	14 d	All had therapeutic nasal suction every third day	30	64	36	2
			Culture-based (nasal suction)			30			
			Amoxicillin/clavulanate (40 mg/kg per day)			12	83	17	
			Amoxicillin/clavulanate (90 mg/kg per day)	14 d		6	100	0	
			Other antibiotics			5	100	0	
Ng et al (2000) ²⁶	5–16	Nasal discharge or blockage for 30–120 d and abnormal sinus radiograph	No antibiotics (negative culture result)		All received budesonide nasal spray 50 µg/nostiril 2 times/day for 91 d	4	50	50	3
			Azithromycin (10 mg/kg per day)	3 d		20	ND ^a	30	
			Amoxicillin/clavulanate (312 mg 3 times/day if aged ≤12 y or 375 mg 3 times/day if aged >12 y)	14 d		21	ND ^a	24	
Dohlman et al (1993) ²⁷	2–16	Mucoid nasal drainage, cough, or poorly controlled asthma for 3 wk–3 mo and abnormal sinus radiograph	Amoxicillin (30–40 mg/kg per day)	21 d	All received oral phenylephrine, phenylpropanolamine, and guaifenesin; all received saline nasal spray	25	72	28	3
			Amoxicillin-clavulanate (30–40 mg/kg per day)	21 d		26	73	27	
			TMP/SMX (8 mg/kg per day)	21 d		26	69	31	
			None			19	63	37	

ND, not determined; TMP/SMX, trimethoprim/sulfamethoxazole.

^a This study only reported “failures.”

isolates and a 6% increase in β -lactamase-producing *H influenzae*, but these findings did not reach statistical significance. The same authors also compared nasopharyngeal (but not sinus) cultures in children before and after licensure of the pneumococcal conjugate vaccine and found similar results.³¹

Antimicrobial Prophylaxis

One small, nonrandomized study of antimicrobial prophylaxis in children with chronic sinusitis was identified.³² Twenty-six of 86 children with chronic sinusitis received prophylaxis for 1 year. There was a 50% reduction in the number of episodes of sinusitis in 19 (73%) subjects. Nearly 25% of the children in the cohort had an underlying immunologic defect, but this discovery did not predict efficacy of prophylaxis. A randomized controlled study of azithromycin prophylaxis for acute recurrent sinusitis in children was identified on ClinicalTrials.gov and began recruiting patients in August 2009.

Duration of Symptoms

As presented previously, data from randomized trials suggest that duration of symptoms alone is not predictive of necessity of antimicrobial therapy. A small case series of complications of rhinosinusitis (almost exclusively orbital cellulitis) in children was recently published.³³ The authors noted that only 3 of 20 children admitted to a single institution over a 10-year period had symptoms of sinusitis for >10 days before hospitalization. On the basis of these data, they concluded that prevention of complications should not be a justification for initiating treatment after 10 days of symptoms.

Imaging

Since publication of the guidelines, there have been additional studies of

children undergoing CT of the head that have confirmed the poor specificity of CT for acute sinusitis.^{34,35} In addition, several small observational studies have assessed the use of MRI to diagnose acute sinusitis.^{36–38} In the first, MRI was performed on a group of children 4 to 7 years of age presenting to a primary care center with any sign of respiratory infection.³⁶ Forty-one (68%) of 60 children had a major abnormality on imaging. Twenty-six children underwent follow-up 2 weeks later. Of these, 18 (69%) still had abnormal MRI findings, although this finding did not correlate with clinical symptoms. Another study by the same authors compared MRI findings in a convenience sample of children without respiratory complaints. Eight of 19 asymptomatic children had abnormal MRI findings.³⁷ A similar study found abnormal sinuses in 14 (31%) of 45 asymptomatic children.³⁸

OTHER PEDIATRIC SINUSITIS GUIDELINES

Published guidelines were identified during the primary literature search. In addition, the Guidelines International Network (www.g-i-n.net) database was searched but yielded no results. Recently published pediatric guidelines for acute bacterial sinusitis are presented in Table 8.^{39–42} These include English-language, pediatric-specific guidelines and other English-language guidelines that included separate recommendations for children. These guidelines were in near-complete concordance with the 2001 AAP guidelines in terms of clinical diagnosis, choice of antimicrobial agents, avoidance of radiographic studies, and avoidance of adjuvant therapies. One exception was that the European position paper recommended topical corticosteroids (in addition to oral antibiotics) as a grade A recommendation.³⁹

The American College of Radiology Appropriateness Criteria, last updated in 2009, are another set of professional recommendations relevant to the diagnosis of sinusitis in children.⁴³ In summary, no radiologic studies are recommended by the American College of Radiology for acute uncomplicated sinusitis. Coronal CT of the paranasal sinuses is recommended for children with symptoms that persist after 10 days of appropriate therapy. Cranial CT with contrast, including the sinuses and orbits, is recommended for suspected complications of sinusitis.

DISCUSSION

The 2001 technical report noted a paucity of high-quality evidence for establishing the diagnosis and management of acute sinusitis in children. Nearly a decade later, data are still limited. Overall, 17 randomized controlled trials of pediatric acute sinusitis were identified. Of these, only 10 studies scored 3 points or higher on the Jadad scale, which is considered indicative of good study design.⁵ These findings are consistent with other recent systematic reviews of pediatric acute sinusitis. A 2002 Cochrane review included data from 6 randomized controlled trials involving 562 children.⁴⁴ However, 2 studies focused on chronic sinusitis and 1 focused on subacute sinusitis. In addition, a recently published meta-analysis of studies comparing antimicrobial therapy versus placebo in all age groups identified only 3 studies that included children, all of which were included in the current review.⁴⁵ The publication of another placebo-controlled trial in 2009 is a significant contribution; however, only 310 children with acute sinusitis (392 if the Kristo study is included) have been studied in placebo-controlled fashion, with inconsistent results. Although meta-analysis techniques are designed to increase sample size and power,

TABLE 8 Summary of Other Published Guidelines for the Management of Acute Sinusitis in Children

Guideline	Antimicrobial Guidelines for Acute Bacterial Sinusitis (Sinus and Allergy Health Partnership, 2004) ³⁹	Cincinnati Children's Hospital Evidence-Based Guideline (2006) ⁴⁰	European Position Paper on Primary Care Diagnosis and Management of Rhinosinusitis and Nasal Polyps (2007) ⁴¹	Guidelines for Treatment of Acute and Subacute Rhinosinusitis in Children (Italy, 2008) ⁴²
Diagnosis	No resolution after 10 d or worsens after 5–7 d with any of the following: nasal drainage, nasal congestion, facial pressure/pain, postnasal drainage, hyposmia/anosmia, fever, cough, fatigue, maxillary dental pain, and ear pressure/fullness	Clinical: at least 10 d without improvement Specific note: character of nasal discharge is not useful	(1) Cold with nasal discharge, daytime cough worsening at night >10 d (2) Cold that seems more severe than usual (3) Cold that was improving but suddenly worsens	(1) URTI without improvement within 10 d (2) URTI with severe symptoms (high fever, purulent rhinorrhea, headache, facial pain) (3) URTI that completely recedes within 3–4 d but recurs within 10 d
Imaging	Not recommended routinely	Not routinely recommended For children with persistent findings or complications, imaging decisions should be made in consultation with consulting subspecialists	Not recommended	Not recommended CT when surgery being considered
Antimicrobials	Mild disease, no recent antibiotics: amoxicillin/clavulanate, amoxicillin, cefpodoxime, cefuroxime, cefdinir For allergies: TMP/SMX, macrolides Moderate disease or mild disease with recent antibiotics: amoxicillin/clavulanate (high-dose), ceftriaxone For allergies, same as above, plus clindamycin	First-line: high-dose amoxicillin or amoxicillin/clavulanate for 10–14 d Second-line: cefuroxime, cefpodoxime, cefdinir For allergies: second-line antibiotics if non-type I reaction Clarithromycin or azithromycin for type I reaction	Recommended: specific agents not discussed	Amoxicillin 50 mg/kg per day If recent antibiotic exposure, school-attendance, or suspicion of antibiotic-resistant pathogens: Amoxicillin/clavulanate (80-90 mg/kg per day), cefuroxime (30 mg/kg per day), or cefaclor (50 mg/kg per day)
Adjuvant therapies	NA	Not recommended (antitussives, mucolytics, inhaled steroids, β_2 -agonists, antihistamines, decongestants)	Topical steroids (in addition to systemic antibiotics) listed as a level Ib recommendation (from at least 1 RCT)	Antihistamines, corticosteroids, decongestants, expectorants, mucolytics, and vasoconstrictors not recommended Antibiotic prophylaxis not recommended
Complications	NA	Consult otolaryngologist and/or ophthalmologist	Immediate referral/hospitalization	Prompt, aggressive, multidisciplinary intervention

This table incorporates pediatric-specific guidelines (Cincinnati, Italy) as well as general guidelines with pediatric-specific recommendations (Sinus and Allergy Health Partnership, European Position Paper). CT, computed tomography; NA, not applicable; RCT, randomized controlled trial; TMP/SMX, trimethoprim/sulfamethoxazole; URTI, upper respiratory tract infection.

these were not pursued given the significant heterogeneity between the studies.

There are no reliable diagnostic criteria to distinguish between children with acute viral and bacterial sinusitis. However, the inclusion and exclusion criteria used in the 2 randomized studies that demonstrated a benefit of antimicrobial therapy compared with placebo offer insight into criteria that may identify children who are likely to benefit from antimicrobial therapy. Qualitatively, greater severity of illness at the time of presentation seems to be

associated with increased likelihood of antimicrobial efficacy.

No studies of the microbiology of acute sinusitis in children have been published since the introduction of the conjugate pneumococcal vaccine. It is reasonable to assume that the same pathogen shifts observed in acute otitis media are found in acute bacterial sinusitis. However, this assumption would not necessarily imply that the treatment outcomes for otitis and sinusitis are the same.

Although the need for and choice of antimicrobial therapy remains controversial,

the short-term adverse effect profiles for common antibacterial agents used in the management of sinusitis seem to be fairly benign. Two studies found no significant differences in adverse events between placebo and antimicrobial therapy.^{8,9} A third reported that, although adverse effects were more common in the treatment group, those events occurring in children who received high-dose amoxicillin/clavulanate were mostly mild and self-limited.⁶ However, the long-term effects of antimicrobial use on resistance patterns at the population level remain unmeasured

and need to be considered in the revised guidelines.

Evidence to support the use of ancillary measures in the management of acute sinusitis in children is limited. Two small, randomized controlled studies demonstrated that children treated with intranasal steroids had better outcomes compared with children treated with systemic decongestants plus antibiotics¹⁸ or antibiotics alone.¹⁷ One of these studies demonstrated that corticosteroids hastened resolution of symptoms, but cure at the end of the study was equivalent. The other

defined acute sinusitis as an infection lasting up to 12 weeks, which may not be applicable to the definition of acute sinusitis used in the AAP guidelines. The efficacy of decongestants and antihistamines for sinusitis has not been proven. Given recent concerns regarding their safety profile in young children, the use of these agents should be avoided.

CONCLUSIONS

There are limited data to guide the diagnosis and management of acute

bacterial sinusitis in children. Although there have been 4 placebo-controlled studies of antimicrobial therapy in children with acute sinusitis, the results of these studies varied. It is clear that some children with sinusitis benefit from antibiotic use and some do not. Diagnostic and treatment guidelines focusing on severity of illness at the time of presentation have the potential to identify children who will benefit from therapy and at the same time minimize unnecessary use of antibiotics.

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Sinusitis Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
— Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Sinusitis
- AAP Patient Education Handout
— *Sinusitis and Your Child*

Action Statement Summary

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

Key Action Statement 1

Clinicians should make a presumptive diagnosis of acute bacterial sinusitis when a child with an acute URI presents with the following:

- Persistent illness, ie, nasal discharge (of any quality) or daytime cough or both lasting more than 10 days without improvement;

OR

- Worsening course, ie, worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement;

OR

- Severe onset, ie, concurrent fever (temperature $\geq 39^{\circ}\text{C}/102.2^{\circ}\text{F}$) and purulent nasal discharge for at least 3 consecutive days (Evidence Quality: B; Recommendation).

Key Action Statement 2A

Clinicians should not obtain imaging studies (plain films, contrast-enhanced computed tomography [CT], MRI, or ultrasonography) to distinguish acute bacterial sinusitis from viral URI (Evidence Quality: B; Strong Recommendation).

Key Action Statement 2B

Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI with contrast whenever a child is suspected of having orbital or central nervous system complications of acute bacterial sinusitis (Evidence Quality: B; Strong Recommendation).

Key Action Statement 3

Initial Management of Acute Bacterial Sinusitis

3A: "Severe onset and worsening course" acute bacterial sinusitis. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course (signs, symptoms, or both) (Evidence Quality: B; Strong Recommendation).

3B: "Persistent illness." The clinician should either prescribe antibiotic therapy OR offer additional outpatient observation for 3 days to children with persistent illness (nasal discharge of any quality or cough or both for at least 10 days without evidence of improvement) (Evidence Quality: B; Recommendation).

Key Action Statement 4

Clinicians should prescribe amoxicillin with or without clavulanate as first-line treatment when a decision has been made to initiate antibiotic treatment of acute bacterial sinusitis (Evidence Quality: B; Recommendation).

Key Action Statement 5A

Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) OR failure to improve (lack of reduction in all presenting signs/symptoms) within 72 hours of initial management (Evidence Quality: C; Recommendation).

Key Action Statement 5B

If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve in 72 hours, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic OR initiate antibiotic treatment of the child initially managed with observation (Evidence Quality: D; Option based on expert opinion, case reports, and reasoning from first principles).

Coding Quick Reference for Sinusitis

ICD-9-CM

461.9 Sinusitis, acute, unspecified

ICD-10-CM

J01.90 Acute sinusitis, unspecified

J01.91 Acute recurrent sinusitis, unspecified

Sinusitis and Your Child



Sinusitis is an inflammation of the lining of the nose and sinuses. It is a very common infection in children.

Viral sinusitis usually accompanies a cold. Allergic sinusitis may accompany allergies such as hay fever. Bacterial sinusitis is a secondary infection caused by the trapping of bacteria in the sinuses during the course of a cold or allergy.

Fluid inside the sinuses

When your child has a viral cold or hay fever, the linings of the nose and sinus cavities swell up and produce more fluid than usual. This is why the nose gets congested and is “runny” during a cold.

Most of the time the swelling disappears by itself as the cold or allergy goes away. However, if the swelling does not go away, the openings that normally allow the sinuses to drain into the back of the nose get blocked and the sinuses fill with fluid. Because the sinuses are blocked and cannot drain properly, bacteria are trapped inside and grow there, causing a secondary infection. Although nose blowing and sniffing may be natural responses to this blockage, when excessive they can make the situation worse by pushing bacteria from the back of the nose into the sinuses.

Is it a cold or bacterial sinusitis?

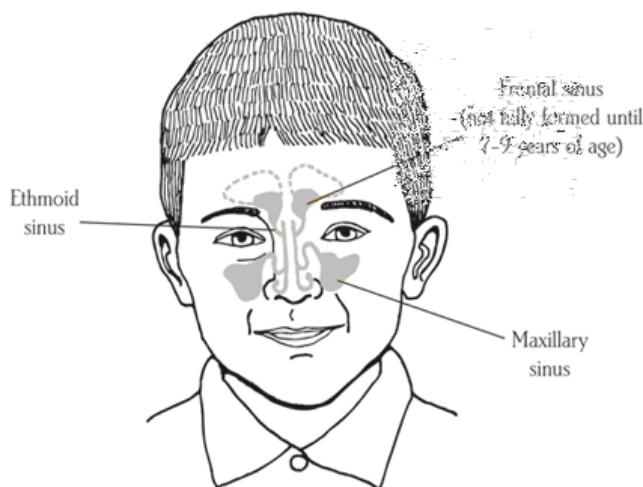
It is often difficult to tell if an illness is just a viral cold or if it is complicated by a bacterial infection of the sinuses.

Generally viral colds have the following characteristics:

- Colds usually last only 5 to 10 days.
- Colds typically start with clear, watery nasal discharge. After a day or 2, it is normal for the nasal discharge to become thicker and white, yellow, or green. After several days, the discharge becomes clear again and dries.
- Colds include a daytime cough that often gets worse at night.
- If a fever is present, it is usually at the beginning of the cold and is generally low grade, lasting for 1 or 2 days.
- Cold symptoms usually peak in severity at 3 or 5 days, then improve and disappear over the next 7 to 10 days.

Signs and symptoms that your child may have bacterial sinusitis include:

- Cold symptoms (nasal discharge, daytime cough, or both) lasting more than 10 days *without improving*
- Thick yellow nasal discharge *and* a fever for at least 3 or 4 days in a row
- A severe headache behind or around the eyes that gets worse when bending over
- Swelling and dark circles around the eyes, especially in the morning
- Persistent bad breath along with cold symptoms (However, this also could be from a sore throat or a sign that your child is not brushing his teeth!)



The linings of the sinuses and the nose always produce some fluid (secretions). This fluid keeps the nose and sinus cavities from becoming too dry and adds moisture to the air that you breathe.

In very rare cases, a bacterial sinus infection may spread to the eye or the central nervous system (the brain). If your child has the following symptoms, call your pediatrician immediately:

- Swelling and/or redness around the eyes, not just in the morning but all day
- Severe headache and/or pain in the back of the neck
- Persistent vomiting
- Sensitivity to light
- Increasing irritability

Diagnosing bacterial sinusitis

It may be difficult to tell a sinus infection from an uncomplicated cold, especially in the first few days of the illness. Your pediatrician will most likely be able to tell if your child has bacterial sinusitis after examining your child and hearing about the progression of symptoms. In older children, when the diagnosis is uncertain, your pediatrician may order computed tomographic (CT) scans to confirm the diagnosis.

Treating bacterial sinusitis

If your child has bacterial sinusitis, your pediatrician may prescribe an antibiotic for at least 10 days. Once your child is on the medication, symptoms should start to go away over the next 2 to 3 days—the nasal discharge will clear and the cough will improve. *Even though your child may seem better, continue to give the antibiotics for the prescribed length of time. Ending the medications too early could cause the infection to return.*

When a diagnosis of sinusitis is made in children with cold symptoms lasting more than 10 days without improving, some doctors may choose to continue observation for another few days. If your child's symptoms worsen during this time or do not improve after 3 days, antibiotics should be started.

If your child's symptoms show no improvement 2 to 3 days after starting the antibiotics, talk with your pediatrician. Your child might need a different medication or need to be re-examined.

Treating related symptoms of bacterial sinusitis

Headache or sinus pain. To treat headache or sinus pain, try placing a warm washcloth on your child's face for a few minutes at a time. Pain medications such as acetaminophen or ibuprofen may also help. (However, do not give your child aspirin. It has been associated with a rare but potentially fatal disease called Reye syndrome.)

Nasal congestion. If the secretions in your child's nose are especially thick, your pediatrician may recommend that you help drain them with saline nose drops. These are available without a prescription or can be made at home by adding 1/4 teaspoon of table salt to an 8-ounce cup of water. Unless advised by your pediatrician, do not use nose drops that contain medications because they can be absorbed in amounts that can cause side effects.

Placing a cool-mist humidifier in your child's room may help keep your child more comfortable. Clean and dry the humidifier daily to prevent bacteria or mold from growing in it (follow the instructions that came with the humidifier). Hot water vaporizers are not recommended because they can cause scalds or burns.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

Remember

If your child has symptoms of a bacterial sinus infection, see your pediatrician. Your pediatrician can properly diagnose and treat the infection and recommend ways to help alleviate the discomfort from some of the symptoms.

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Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

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- *Clinical Practice Guideline*
- *Technical Report*
 - *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



Readers of this clinical practice guideline are urged to review the technical report to enhance the evidence-based decision-making process. The full technical report is available following the clinical practice guideline and on the companion CD-ROM.

CLINICAL PRACTICE GUIDELINE

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

abstract

FREE

OBJECTIVES: This revised clinical practice guideline, intended for use by primary care clinicians, provides recommendations for the diagnosis and management of the obstructive sleep apnea syndrome (OSAS) in children and adolescents. This practice guideline focuses on uncomplicated childhood OSAS, that is, OSAS associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child who is being treated in the primary care setting.

METHODS: Of 3166 articles from 1999–2010, 350 provided relevant data. Most articles were level II–IV. The resulting evidence report was used to formulate recommendations.

RESULTS AND CONCLUSIONS: The following recommendations are made. (1) All children/adolescents should be screened for snoring. (2) Polysomnography should be performed in children/adolescents with snoring and symptoms/signs of OSAS; if polysomnography is not available, then alternative diagnostic tests or referral to a specialist for more extensive evaluation may be considered. (3) Adenotonsillectomy is recommended as the first-line treatment of patients with adenotonsillar hypertrophy. (4) High-risk patients should be monitored as inpatients postoperatively. (5) Patients should be reevaluated postoperatively to determine whether further treatment is required. Objective testing should be performed in patients who are high risk or have persistent symptoms/signs of OSAS after therapy. (6) Continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if OSAS persists postoperatively. (7) Weight loss is recommended in addition to other therapy in patients who are overweight or obese. (8) Intranasal corticosteroids are an option for children with mild OSAS in whom adenotonsillectomy is contraindicated or for mild postoperative OSAS. *Pediatrics* 2012;130:576–584

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is a common condition in childhood and can result in severe complications if left untreated. In 2002, the American Academy of Pediatrics (AAP) published a practice guideline for the diagnosis and management of childhood OSAS.¹ Since that time, there has been a considerable increase in publications and research on the topic; thus, the guidelines have been revised.

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KEY WORDS

snoring, sleep-disordered breathing, adenotonsillectomy, continuous positive airway pressure

ABBREVIATIONS

AAP—American Academy of Pediatrics

AHI—apnea hypopnea index

CPAP—continuous positive airway pressure

OSAS—obstructive sleep apnea syndrome

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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The purposes of this revised clinical practice guideline are to (1) increase the recognition of OSAS by primary care clinicians to minimize delay in diagnosis and avoid serious sequelae of OSAS; (2) evaluate diagnostic techniques; (3) describe treatment options; (4) provide guidelines for follow-up; and (5) discuss areas requiring further research. The recommendations in this statement do not indicate an exclusive course of treatment. Variations, taking into account individual circumstances, may be appropriate.

This practice guideline focuses on uncomplicated childhood OSAS—that is, the OSAS associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child who is being treated in the primary care setting. This guideline specifically excludes infants younger than 1 year of age, patients with central apnea or hypoventilation syndromes, and patients with OSAS associated with other medical disorders, including but not limited to Down syndrome, craniofacial anomalies, neuromuscular disease (including cerebral palsy), chronic lung disease, sickle cell disease, metabolic disease, or laryngomalacia. These important patient populations are too complex to discuss within the scope of this article and require consultation with a pediatric subspecialist.

Additional information providing justification for the key action statements and a detailed review of the literature are provided in the accompanying technical report available online.²

METHODS OF GUIDELINE DEVELOPMENT

Details of the methods of guideline development are included in the accompanying technical report.² The AAP selected a subcommittee composed of pediatricians and other experts in the fields of sleep medicine, pulmonology, and otolaryngology, as well as experts

from epidemiology and pediatric practice to develop an evidence base of literature on this topic. The committee included liaison members from the AAP Section on Otolaryngology-Head and Neck Surgery, American Thoracic Society, American Academy of Sleep Medicine, American College of Chest Physicians, and the National Sleep Foundation. Committee members signed forms disclosing conflicts of interest.

An automated search of the literature on childhood OSAS from 1999 to 2008 was performed by using 5 scientific literature search engines.² The medical subject heading terms that were used in all fields were snoring, apnea, sleep-disordered breathing, sleep-related breathing disorders, upper airway resistance, polysomnography, sleep study, adenoidectomy, tonsillectomy, continuous positive airway pressure, obesity, adiposity, hypopnea, hypoventilation, cognition, behavior, and neuropsychology. Reviews, case reports, letters to the editor, and abstracts were not included. Non-English-language articles, animal studies, and studies relating to infants younger than 1 year and to special populations (eg, children with craniofacial anomalies or sickle cell disease) were excluded. In several steps, a total of 3166 hits was reduced to 350 articles, which underwent detailed review.² Committee members selectively updated this literature search for articles published from 2008 to 2011 specific to guideline categories. Details of the literature grading system are available in the accompanying technical report.

Since publication of the previous guidelines, there has been an improvement in the quality of OSAS studies in the literature; however, there remain few randomized, blinded, controlled studies. Most studies were questionnaire or polysomnography based. Many studies used standard definitions for pediatric polysomnography scoring, but

the interpretation of polysomnography (eg, the apnea hypopnea index [AHI] criterion used for diagnosis or to determine treatment) varied widely. The guideline notes the quality of evidence for each key action statement. Additional details are available in the technical report.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement, “Classifying Recommendations for Clinical Practice Guidelines,”³ was followed in designating levels of recommendation (see Fig 1 and Table 1).

DEFINITION

This guideline defines OSAS in children as a “disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns,”⁴ accompanied by symptoms or signs, as listed in Table 2. Prevalence rates based on level I and II studies range from 1.2% to 5.7%.^{5–7} Symptoms include habitual snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems. Daytime sleepiness may occur, but is uncommon in young children. OSAS is associated with neurocognitive impairment, behavioral problems, failure to thrive, hypertension, cardiac dysfunction, and systemic inflammation. Risk factors include adenotonsillar hypertrophy, obesity, craniofacial anomalies, and neuromuscular disorders. Only the first 2 risk factors are

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)	Option	
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation Recommendation	

FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT, randomized controlled trial; Rec, recommendation.

discussed in this guideline. In this guideline, obesity is defined as a BMI >95th percentile for age and gender.⁸

KEY ACTION STATEMENTS

Key Action Statement 1: Screening for OSAS

As part of routine health maintenance visits, clinicians should inquire whether the child or adolescent snores. If the answer is affirmative or if a child or adolescent presents with signs or symptoms of OSAS (Table 2), clinicians should perform

a more focused evaluation. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 1

- Aggregate evidence quality: B
- Benefit: Early identification of OSAS is desirable, because it is a high-prevalence condition, and identification and treatment can result in alleviation of current symptoms, improved quality of life, prevention of sequelae, education of parents, and decreased health care utilization.

- Harm: Provider time, patient and parent time.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists believe that identification of a serious medical condition outweighs the time expenditure necessary for screening.
- Role of patient preferences: None.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Almost all children with OSAS snore,^{9–11} although caregivers frequently do not volunteer this information at medical visits.¹² Thus, asking about snoring at each health maintenance visit (as well as at other appropriate times, such as when evaluating for tonsillitis) is a sensitive, albeit nonspecific, screening measure that is quick and easy to perform. Snoring is common in children and adolescents; however, OSAS is less common. Therefore, an affirmative answer should be followed by a detailed history and examination to determine whether further evaluation for OSAS is needed (Table 2); this clinical evaluation alone

TABLE 1 Definitions and Recommendation Implications

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	It would be prudent for clinicians to follow a recommendation, but they should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

TABLE 2 Symptoms and Signs of OSAS

History
Frequent snoring (≥ 3 nights/wk)
Labored breathing during sleep
Gasps/snorting noises/observed episodes of apnea
Sleep enuresis (especially secondary enuresis) ^a
Sleeping in a seated position or with the neck hyperextended
Cyanosis
Headaches on awakening
Daytime sleepiness
Attention-deficit/hyperactivity disorder
Learning problems
Physical examination
Underweight or overweight
Tonsillar hypertrophy
Adenoidal facies
Micrognathia/retrognathia
High-arched palate
Failure to thrive
Hypertension

^a Enuresis after at least 6 mo of continence.

does not establish the diagnosis (see technical report). Occasional snoring, for example, with an upper respiratory tract infection, is less of a concern than snoring that occurs at least 3 times a week and is associated with any of the symptoms or signs listed in Table 2.

Key Action Statement 2A: Polysomnography

If a child or adolescent snores on a regular basis and has any of the complaints or findings shown in Table 2, clinicians should either (1) obtain a polysomnogram (Evidence Quality A, Key Action strength: Recommendation) OR (2) refer the patient to a sleep specialist or otolaryngologist for a more extensive evaluation (Evidence quality D, Key Action strength: Option). (Evidence Quality: Grade A for polysomnography; Grade D for specialist referral, Recommendation Strength: Recommendation.)

Evidence Profile KAS 2A: Polysomnography

- Aggregate evidence quality: A
- Benefits: Establish diagnosis and determine severity of OSAS.

- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists weighed the value of establishing a diagnosis as more important than the minor potential harms listed.
- Role of patient preferences: Small because of preponderance of evidence that polysomnography is the most accurate way to make a diagnosis.
- Exclusions: See Key Action Statement 2B regarding lack of availability.
- Intentional vagueness: None.
- Strength: Recommendation.

Evidence Profile KAS 2A: Referral

- Aggregate evidence quality: D
- Benefits: Subspecialist may be better able to establish diagnosis and determine severity of OSAS.
- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists weighed the value of establishing a diagnosis as more important than the minor potential harms listed.
- Role of patient preferences: Large.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Although history and physical examination are useful to screen patients and determine which patients need further investigation for OSAS, the sensitivity and specificity of the history and physical examination are poor (see accompanying technical report). Physical examination when the child is awake may be normal, and the size of the tonsils cannot be used to predict the presence of OSAS in an individual child. Thus, objective testing is required. The gold standard test

is overnight, attended, in-laboratory polysomnography (sleep study). This is a noninvasive test involving the measurement of a number of physiologic functions overnight, typically including EEG; pulse oximetry; oronasal airflow, abdominal and chest wall movements, partial pressure of carbon dioxide (P_{CO_2}); and video recording.¹³ Specific pediatric measuring and scoring criteria should be used.¹³ Polysomnography will demonstrate the presence or absence of OSAS. Polysomnography also demonstrates the severity of OSAS, which is helpful in planning treatment and in postoperative short- and long-term management.

Key Action Statement 2B: Alternative Testing

If polysomnography is not available, then clinicians may order alternative diagnostic tests, such as nocturnal video recording, nocturnal oximetry, daytime nap polysomnography, or ambulatory polysomnography. (Evidence Quality: Grade C, Recommendation Strength: Option.)

Evidence Profile KAS 2B

- Aggregate evidence quality: C
- Benefit: Varying positive and negative predictive values for establishing diagnosis.
- Harm: False-negative and false-positive results may underestimate or overestimate severity, expense, time, anxiety/discomfort.
- Benefits-harms assessment: Equilibrium of benefits and harms.
- Value judgments: Opinion of the panel that some objective testing is better than none. Pragmatic decision based on current shortage of pediatric polysomnography facilities (this may change over time).
- Role of patient preferences: Small, if choices are limited by availability;

families may choose to travel to centers where more extensive facilities are available.

- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Although polysomnography is the gold standard for diagnosis of OSAS, there is a shortage of sleep laboratories with pediatric expertise. Hence, polysomnography may not be readily available in certain regions of the country. Alternative diagnostic tests have been shown to have weaker positive and negative predictive values than polysomnography, but nevertheless, objective testing is preferable to clinical evaluation alone. If an alternative test fails to demonstrate OSAS in a patient with a high pretest probability, full polysomnography should be sought.

Key Action Statement 3: Adenotonsillectomy

If a child is determined to have OSAS, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery (see Table 3), the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSAS but does not have adenotonsillar hypertrophy, other treatment should be considered (see Key Action Statement 6). Clinical judgment is required to determine the benefits of adenotonsillectomy compared with other treatments in obese children with varying degrees of adenotonsillar hypertrophy. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 3

- Aggregate evidence quality: B
- Benefit: Improve OSAS and accompanying symptoms and sequelae.

- Harm: Pain, anxiety, dehydration, anesthetic complications, hemorrhage, infection, postoperative respiratory difficulties, velopharyngeal incompetence, nasopharyngeal stenosis, death.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel sees the benefits of treating OSAS as more beneficial than the low risk of serious consequences.
- Role of patient preferences: Low; continuous positive airway pressure (CPAP) is an option but involves prolonged, long-term treatment as compared with a single, relatively low-risk surgical procedure.
- Exclusions: See Table 3.
- Intentional vagueness: None.
- Strength: Recommendation.

Adenotonsillectomy is very effective in treating OSAS. Adenoidectomy or tonsillectomy alone may not be sufficient, because residual lymphoid tissue may contribute to persistent obstruction. In otherwise healthy children with adenotonsillar hypertrophy, adenotonsillectomy is associated with improvements in symptoms and sequelae of OSAS. Postoperative polysomnography typically shows a major decrease in the number of obstructive events, although some obstructions may still be present. Although obese children may have less satisfactory results, many will be adequately treated with

TABLE 3 Contraindications for Adenotonsillectomy

Absolute contraindications
No adenotonsillar tissue (tissue has been surgically removed)
Relative contraindications
Very small tonsils/adenoid
Morbid obesity and small tonsils/adenoid
Bleeding disorder refractory to treatment
Submucous cleft palate
Other medical conditions making patient medically unstable for surgery

adenotonsillectomy; however, further research is needed to determine which obese children are most likely to benefit from surgery. In this population, the benefits of a 1-time surgical procedure, with a small but real risk of complications, need to be weighed against long-term treatment with CPAP, which is associated with discomfort, disruption of family lifestyle, and risks of poor adherence. Potential complications of adenotonsillectomy are shown in Table 4. Although serious complications (including death) may occur, the rate of these complications is low, and the risks of complications need to be weighed against the consequences of untreated OSAS. In general, a 1-time only procedure with a relatively low morbidity is preferable to lifelong treatment with CPAP; furthermore, the efficacy of CPAP is limited by generally suboptimal adherence. Other treatment options, such as anti-inflammatory medications, weight loss, or tracheostomy, are less effective, are difficult to achieve, or have higher morbidity, respectively.

Key Action Statement 4: High-Risk Patients Undergoing Adenotonsillectomy

Clinicians should monitor high-risk patients (Table 5) undergoing adenotonsillectomy as inpatients postoperatively. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

TABLE 4 Risks of Adenotonsillectomy

Minor
Pain
Dehydration attributable to postoperative nausea/vomiting and poor oral intake
Major
Anesthetic complications
Acute upper airway obstruction during induction or emergence from anesthesia
Postoperative respiratory compromise
Hemorrhage
Velopharyngeal incompetence
Nasopharyngeal stenosis
Death

TABLE 5 Risk Factors for Postoperative Respiratory Complications in Children With OSAS Undergoing Adenotonsillectomy

Younger than 3 y of age
Severe OSAS on polysomnography ^a
Cardiac complications of OSAS
Failure to thrive
Obesity
Craniofacial anomalies ^b
Neuromuscular disorders ^b
Current respiratory infection

^a It is difficult to provide exact polysomnographic criteria for severity, because these criteria will vary depending on the age of the child; additional comorbidities, such as obesity, asthma, or cardiac complications of OSAS; and other polysomnographic criteria that have not been evaluated in the literature, such as the level of hypercapnia and the frequency of desaturation (as compared with lowest oxygen saturation). Nevertheless, on the basis of published studies (primarily Level III, see Technical Report), it is recommended that all patients with a lowest oxygen saturation <80% (either on preoperative polysomnography or during observation in the recovery room postoperatively) or an AHI $\geq 24/h$ be observed as inpatients postoperatively as they are at increased risk for postoperative respiratory compromise. Additionally, on the basis of expert consensus, it is recommended that patients with significant hypercapnia on polysomnography (peak $P_{CO_2} \geq 60$ mm Hg) be admitted postoperatively. The committee noted that that most published studies were retrospective and not comprehensive, and therefore these recommendations may change if higher-level studies are published. Clinicians may decide to admit patients with less severe polysomnographic abnormalities based on a constellation of risk factors (age, comorbidities, and additional polysomnographic factors) for a particular individual.

^b Not discussed in these guidelines.

Evidence Profile KAS 4

- Aggregate evidence quality: B
- Benefit: Effectively manage severe respiratory compromise and avoid death.
- Harm: Expense, time, anxiety.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel believes that early recognition of any serious adverse events is critically important.
- Role of patient preferences: Minimal; this is an important safety issue.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Patients with OSAS may develop respiratory complications, such as worsening

of OSAS or pulmonary edema, in the immediate postoperative period. Death attributable to respiratory complications in the immediate postoperative period has been reported in patients with severe OSAS. Identified risk factors are shown in Table 5. High-risk patients should undergo surgery in a center capable of treating complex pediatric patients. They should be hospitalized overnight for close monitoring postoperatively. Children with an acute respiratory infection on the day of surgery, as documented by fever, cough, and/or wheezing, are at increased risk of postoperative complications and, therefore, should be rescheduled or monitored closely postoperatively. Clinicians should decide on an individual basis whether these patients should be rescheduled, taking into consideration the severity of OSAS in the particular patient and keeping in mind that many children with adenotonsillar hypertrophy have chronic rhinorrhea and nasal congestion, even in the absence of viral infections.

Key Action Statement 5: Reevaluation

Clinicians should clinically reassess all patients with OSAS for persisting signs and symptoms after therapy to determine whether further treatment is required. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 5A

- Aggregate evidence quality: B
- Benefit: Determine effects of treatment.
- Harm: Expense, time.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Data show that a significant proportion of children continue to have abnormalities postoperatively; therefore, the panel deter-

mined that the benefits of follow-up outweigh the minor inconveniences.

- Role of patient preferences: Minimal; follow-up is good clinical practice.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Clinicians should reassess OSAS-related symptoms and signs (Table 2) after 6 to 8 weeks of therapy to determine whether further evaluation and treatment are indicated. Objective data regarding the timing of the postoperative evaluation are not available. Most clinicians recommend reevaluation 6 to 8 weeks after treatment to allow for healing of the operative site and to allow time for upper airway, cardiac, and central nervous system recovery. Patients who remain symptomatic should undergo objective testing (see Key Action Statement 2) or be referred to a sleep specialist for further evaluation.

Key Action Statement 5B: Reevaluation of High-Risk Patients

Clinicians should reevaluate high-risk patients for persistent OSAS after adenotonsillectomy, including those who had a significantly abnormal baseline polysomnogram, have sequelae of OSAS, are obese, or remain symptomatic after treatment, with an objective test (see Key Action Statement 2) or refer such patients to a sleep specialist. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 5B

- Aggregate evidence quality: B
- Benefit: Determine effects of treatment.
- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.

- Value judgments: Given the panel's concerns about the consequences of OSAS and the frequency of postoperative persistence in high-risk groups, the panel believes that the follow-up costs are outweighed by benefits of recognition of persistent OSAS. A minority of panelists believed that all children with OSAS should have follow-up polysomnography because of the high prevalence of persistent postoperative abnormalities on polysomnography, but most panelists believed that persistent polysomnographic abnormalities in uncomplicated children with mild OSAS were usually mild in patients who were asymptomatic after surgery.
- Role of patient preferences: Minimal. Further evaluation is needed to determine the need for further treatment.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Numerous studies have shown that a large proportion of children at high risk continue to have some degree of OSAS postoperatively^{10,13,14}; thus, objective evidence is required to determine whether further treatment is necessary.

Key Action Statement 6: CPAP

Clinicians should refer patients for CPAP management if symptoms/signs (Table 2) or objective evidence of OSAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 6

- Aggregate evidence quality: B
 - Benefit: Improve OSAS and accompanying symptoms and sequelae.
 - Harm: Expense, time, anxiety; parental sleep disruption; nasal and skin adverse effects; possible midface remodeling; extremely rare serious pressure-related complications, such as pneumothorax; poor adherence.
 - Benefits-harms assessment: Preponderance of benefit over harm.
 - Value judgments: Panelists believe that CPAP is the most effective treatment of OSAS that persists postoperatively and that the benefits of treatment outweigh the adverse effects. Other treatments (eg, rapid maxillary expansion) may be effective in specially selected patients.
 - Role of patient preferences: Other treatments may be effective in specially selected patients.
 - Exclusions: Rare patients at increased risk of severe pressure complications.
 - Intentional vagueness: None.
 - Policy level: Recommendation.
- CPAP therapy is delivered by using an electronic device that delivers air at positive pressure via a nasal mask, leading to mechanical stenting of the airway and improved functional residual capacity in the lungs. There is no clear advantage of using bilevel pressure over CPAP.¹⁵ CPAP should be managed by an experienced and skilled clinician with expertise in its use in children. CPAP pressure requirements vary among individuals and change over time; thus, CPAP must be titrated in the sleep laboratory before prescribing the device and periodically readjusted thereafter. Behavioral modification therapy may be required, especially for young children or those with developmental delays. Objective monitoring of adherence, by using the equipment software, is important. If adherence is suboptimal, the clinician should institute measures to improve adherence (such as behavioral modification, or treating side effects of

CPAP) and institute alternative treatments if these measures are ineffective.

Key Action Statement 7: Weight Loss

Clinicians should recommend weight loss in addition to other therapy if a child/adolescent with OSAS is overweight or obese. (Evidence Quality: Grade C, Recommendation Strength: Recommendation.)

Evidence Profile KAS 7

- Aggregate evidence quality: C
- Benefit: Improve OSAS and accompanying symptoms and sequelae; non-OSAS-related benefits of weight loss.
- Harm: Hard to achieve and maintain weight loss.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel agreed that weight loss is beneficial for both OSAS and other health issues, but clinical experience suggests that weight loss is difficult to achieve and maintain, and even effective weight loss regimens take time; therefore, additional treatment is required in the interim.
- Role of patient preferences: Strong role for patient and family preference regarding nutrition and exercise.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Weight loss has been shown to improve OSAS,^{16,17} although the degree of weight loss required has not been determined. Because weight loss is a slow and unreliable process, other treatment modalities (such as adenotonsillectomy or CPAP therapy) should be instituted until sufficient weight loss has been achieved and maintained.

Key Action Statement 8: Intranasal Corticosteroids

Clinicians may prescribe topical intranasal corticosteroids for children with mild OSAS in whom adenotonsillectomy is contraindicated or for children with mild post-operative OSAS. (Evidence Quality: Grade B, Recommendation Strength: Option.)

Evidence Profile KAS 8

- Aggregate evidence quality: B
- Benefit: Improves mild OSAS and accompanying symptoms and sequelae.
- Harm: Some subjects may not have an adequate response. It is not known whether therapeutic effect persists long-term; therefore, long-term observation is required. Low risk of steroid-related adverse effects.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel agreed that intranasal steroids provide a less invasive treatment than surgery or CPAP and, therefore, may be preferred in some cases despite lower efficacy and lack of data on long-term efficacy.
- Role of patient preferences: Moderate role for patient and family preference if OSAS is mild.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Mild OSAS is defined, for this indication, as an AHI <5 per hour, on the basis of studies on intranasal corticosteroids described in the accompanying technical report.² Several studies have shown that the use of intranasal steroids decreases the degree of OSAS; however, although

OSAS improves, residual OSAS may remain. Furthermore, there is individual variability in response to treatment, and long-term studies have not been performed to determine the duration of improvement. Therefore, nasal steroids are not recommended as a first-line therapy. The response to treatment should be measured objectively after a course of treatment of approximately 6 weeks. Because the long-term effect of this treatment is unknown, the clinician should continue to observe the patient for symptoms of recurrence and adverse effects of corticosteroids.

AREAS FOR FUTURE RESEARCH

A detailed list of research recommendations is provided in the accompanying technical report.² There is a great need for further research into the prevalence of OSAS, sequelae of OSAS, best treatment methods, and the role of obesity. In particular, well-controlled, blinded studies, including randomized controlled trials of treatment, are needed to determine the best care for children and adolescents with OSAS.

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TECHNICAL REPORT

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

abstract

FREE

OBJECTIVE: This technical report describes the procedures involved in developing recommendations on the management of childhood obstructive sleep apnea syndrome (OSAS).

METHODS: The literature from 1999 through 2011 was evaluated.

RESULTS AND CONCLUSIONS: A total of 3166 titles were reviewed, of which 350 provided relevant data. Most articles were level II through IV. The prevalence of OSAS ranged from 0% to 5.7%, with obesity being an independent risk factor. OSAS was associated with cardiovascular, growth, and neurobehavioral abnormalities and possibly inflammation. Most diagnostic screening tests had low sensitivity and specificity. Treatment of OSAS resulted in improvements in behavior and attention and likely improvement in cognitive abilities. Primary treatment is adenotonsillectomy (AT). Data were insufficient to recommend specific surgical techniques; however, children undergoing partial tonsillectomy should be monitored for possible recurrence of OSAS. Although OSAS improved postoperatively, the proportion of patients who had residual OSAS ranged from 13% to 29% in low-risk populations to 73% when obese children were included and stricter polysomnographic criteria were used. Nevertheless, OSAS may improve after AT even in obese children, thus supporting surgery as a reasonable initial treatment. A significant number of obese patients required intubation or continuous positive airway pressure (CPAP) postoperatively, which reinforces the need for inpatient observation. CPAP was effective in the treatment of OSAS, but adherence is a major barrier. For this reason, CPAP is not recommended as first-line therapy for OSAS when AT is an option. Intranasal steroids may ameliorate mild OSAS, but follow-up is needed. Data were insufficient to recommend rapid maxillary expansion. *Pediatrics* 2012;130:e714–e755

INTRODUCTION

This technical report describes in detail the procedures involved in developing the recommendations for the updated clinical practice guideline on childhood obstructive sleep apnea syndrome (OSAS).¹

The clinical practice guideline is primarily aimed at pediatricians and other primary care clinicians (family physicians, nurse practitioners,

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KEY WORDS

adenotonsillectomy, continuous positive airway pressure, sleep-disordered breathing, snoring

ABBREVIATIONS

AAP—American Academy of Pediatrics
ADHD—attention-deficit/hyperactivity disorder
AHI—apnea hypopnea index
AT—adenotonsillectomy
BP—blood pressure
BPAP—bilevel positive airway pressure
CBCL—Child Behavior Checklist
CPAP—continuous positive airway pressure
CRP—C-reactive protein
ECG—electrocardiography
HOMA—homeostatic model assessment
HS—habitual snoring
IL—interleukin
OSAS—obstructive sleep apnea syndrome
PAP—positive airway pressure
PSG—polysomnography
PT—partial tonsillectomy
QoL—quality of life
RDI—respiratory distress index
SDB—sleep-disordered breathing
SES—socioeconomic status
SpO₂—oxygen saturation
URI—upper respiratory tract infection

(Continued on last page)

and physician assistants) who treat children. The secondary audience for the guideline includes sleep medicine specialists, pediatric pulmonologists, neurologists, otolaryngologists, and developmental/behavioral pediatricians.

The primary focus of the committee was on OSAS in childhood.² The committee focused on otherwise healthy children who had adenotonsillar hypertrophy or obesity as underlying risk factors. Complex populations, including infants <1 year of age and children who had other medical conditions (eg, craniofacial anomalies, genetic or metabolic syndromes, neuromuscular disease, laryngomalacia, sickle cell disease), were excluded because these patients will typically require subspecialty referral.

Two professional studies recently published related guidelines: the American Academy of Otolaryngology–Head and Neck Surgery³ and the American Academy of Sleep Medicine.⁴ These guidelines have similar recommendations to many of the recommendations in the American Academy of Pediatrics (AAP) guideline.

The recommendations in this statement do not indicate an exclusive course of treatment. Variations, taking into account individual circumstances, may be appropriate.

METHODS

Literature Search

A literature search was performed that included English-language articles, children and adolescents aged 1 through 17.9 years, and publication between 1999 and 2008. Animal studies, abstracts, letters, case reports, and reviews were excluded. The Medical Subject Heading terms that were used in all fields were snoring, apnea, sleep-disordered breathing (SDB), sleep-related breathing disorders, upper

airway resistance, polysomnography (PSG), sleep study, adenoidectomy, tonsillectomy, continuous positive airway pressure (CPAP), obesity, adiposity, hypopnea, hypoventilation, cognition, behavior, and neuropsychology. Search engines used were PubMed, Scopus, Ovid, PsycINFO, EBSCO (including Health Source [Nursing], Child Development and Adolescent Studies), and CINAHL. Articles covering special populations (eg, infants aged <1 year, those with craniofacial anomalies or syndromes) were excluded during the title and abstract reviews.

Titles and available abstracts of articles found by the literature search were reviewed by the committee members in several rounds (see Results). In the first round, duplicates and erroneous hits from the literature search were excluded. In the second round, titles were reviewed for relevancy by 2 committee members. Articles with relevant titles were then reviewed by 2 reviewers each, on the basis of the abstract. Because of the large number of remaining articles, text-mining (Statistica, StatSoft version 9; StatSoft, Inc, Tulsa, OK) was performed on the method section of the articles to reduce the large amount of articles for the final step of quality assessment. Text-mining is the combined, automated process of analyzing unstructured, natural language text to discover information and knowledge that are typically difficult to retrieve.⁵

Unfortunately, text-mining revealed that few articles reported research methods, such as the study design (eg, clinical case series, retrospective, observational, clinical experiment), blinding of the assessment, and recruitment and/or scoring, that could have been applied for further selection. A manual screening of the questionable articles after text-mining resulted in a pool of 605 articles. The committee decided on a final round of title selection; that is, each

member was assigned a random batch of articles and selected titles based on relevance with respect to the guideline categories. These remaining articles were each reviewed and graded by a committee member, as detailed here. Because of the large volume of articles requiring detailed evaluation, some committee members recruited trainees and colleagues to assist them in the performance of these reviews, under their supervision. Jason Caboot, June Chan, Mary Currie, Fiona Healy, Maureen Josephson, Sofia Konstantinopoulou, H. Madan Kumar, Roberta Leu, Darius Loghmanee, Rajeev Bhatia, Argyri Petrocheilou, Harsha Vardhan, and Colleen Walsh participated. A literature search of more recent articles (2008–2011) was performed by individual committee members, per guideline category, and discussed during the committee meeting.

As would be expected from any panel of experts in a field, some of the citations were the work of the panel members. For this reason, a varied panel, including general pediatricians, pulmonologists, otolaryngologists, and sleep medicine physicians, was arranged to provide balance. For initial guideline drafts, committee members were assigned sections of the report that were not directly in their area of research, and the evidence, search results, and conclusions thereof were discussed by all committee members at a face-to-face meeting. Subsequent drafts of the guidelines and technical report were reviewed by all committee members.

Quality Assessment

The previous literature review form⁶ was modified to include the evidence grading system developed by the American Academy of Neurology for the assessment of clinical utility of diagnostic tests (Table 1).⁷ A specific customized software (OSA Taskforce;

TABLE 1 Evidence Grading System⁷

Level	Description
I	Evidence provided by a prospective study in a broad spectrum of persons who have the suspected condition, by using a reference (gold) standard for case definition, in which the test is applied in a blinded fashion, and enabling the assessment of appropriate test of diagnostic accuracy. All persons undergoing the diagnostic test have the presence or absence of the disease determined. Level I studies are judged to have a low risk of bias.
II	Evidence provided by a prospective study of a narrow spectrum of persons who have the suspected condition, or a well-designed retrospective study of a broad spectrum of persons who have an established condition (by gold standard) compared with a broad spectrum of controls, in which the test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy. Level II studies are judged to have a moderate risk of bias.
III	Evidence provided by a retrospective study in which either persons who have the established condition or controls are of a narrow spectrum, and in which the reference standard, if not objective, is applied by someone other than the person who performed (interpreted) the test. Level III studies are judged to have a moderate to high risk of bias.
IV	Any study design where the test is not applied in an independent evaluation or evidence is provided by expert opinion alone or in descriptive case series without controls. There is no blinding or there may be inadequate blinding. The spectrum of persons tested may be broad or narrow. Level IV studies are judged to have a very high risk of bias.

copyright Francesco Rundo and Karen Spruyt) was developed for the literature review form to standardize this part of the process. Of note, the quality assessment levels were comparable to the grading levels applied previously.^{8,9} The quality assessment applied involved 4 tiers of evidence, with level I studies being judged to have a low risk of bias and level IV studies judged to have a very high level of bias. A weaker level of evidence indicates the need to integrate greater clinical judgment when applying results to clinical decision-making. The committee's quality assessment of data took into account not only the levels of evidence in relevant articles but also the number of articles identified, the magnitude and direction of various findings, and whether articles demonstrated convergent or divergent conclusions.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit

and harm that is anticipated when the recommendation is followed. The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines"¹⁰ was followed in designating levels of recommendations (Fig 1, Table 2).

RESULTS OF LITERATURE SEARCH

The automated Medical Subject Heading search resulted in 3166 hits. After duplicates and erroneous hits were excluded, 2395 hits fulfilled the criteria. After title review, 1091 articles were accepted, with a 0.70 interrater agreement between the 2 reviewers. These remaining articles were reviewed on the basis of the abstract, which resulted in 757 articles remaining, with a 0.60 agreement rate between reviewers. A final decision on those without agreement was made by the chairperson of the committee. Text-mining, although not helpful in reducing the number of articles for further evaluation, illustrated the spectrum of topics covered by the articles (Table 3). A manual screening of the questionable articles after text-mining resulted in a pool of 605 articles. The final round of title selection resulted in 397 articles for

detailed review. An additional 47 articles were found to not meet criteria during the detailed review. Thus, a total of 350 articles were included.

On the basis of the final 350 articles, one-third were epidemiologic studies, 26% were diagnostic studies, and 23% were treatment studies. Table 4 lists the type of study design; 34% of studies were descriptive and 32% were nonrandomized concurrent cohort series. PSG was the diagnostic method used for 57% of the articles, whereas 45% used questionnaires. The sample size varied from 9 to 6742 subjects. Figure 2 shows the level of evidence of the articles; 76% of studies were level III or IV. The majority of studies did not include a control group, which degraded the studies to level III or IV. Few studies applied any form of blinding.

Conclusion

There has been a large increase in the number of published studies since the initial guideline was published. However, there are few randomized, blinded, controlled studies. Most articles evaluated were level III or IV, and many studies were hampered by the lack of a control group. In most studies, blinding was not present or not reported. From a methodologic standpoint, a clear need for randomized clinical trials with blinding is evident.

TERMINOLOGY

OSAS in children is defined as a "disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns,"² accompanied by symptoms or signs as listed in Table 2 of the accompanying guideline. In this document, the term SDB is used to encompass

both snoring and OSAS when studies did not distinguish between these entities.

PREVALENCE OF OSAS

The original clinical practice guideline found a prevalence of OSAS of 2% (3 studies) and a prevalence of habitual snoring (HS) of 3% to 12% (7 studies). Since publication of the original guideline, 10 studies (in 12 separate articles) used the gold standard of conventional overnight laboratory PSG to diagnose OSAS (Table 5). These

studies were all levels I through IV, depending on the size and characteristics of the sample population, and represented many countries and age groups. They used various criteria, not all of which are standard, to diagnose OSAS. Many of the studies had a small sample size and/or studied only a selected high-risk sample of the population. Despite these limitations, the 10 studies found a prevalence of OSAS in the general pediatric population of 0% to 5.7%. Three studies to note were those of Bixler et al¹¹ from the United States, Li et al¹² from China,

and O'Brien et al¹³ from the United States. These 3 studies (levels I–II) had large sample sizes from the general pediatric population and reported OSAS prevalence rates of 1.2% to 5.7%. Six studies investigated the prevalence of OSAS by using various ambulatory studies rather than full, laboratory-based PSG (Table 6). Although the sample sizes were generally larger, home studies are not considered the gold standard of diagnosis and were thus level III. These studies found an OSAS prevalence of 0.8% to 24%. The 2 outliers (at 12% and 24%)^{14,15} used more liberal criteria to diagnose OSAS. Excluding those studies, the OSAS prevalence was 0.8% to 2.8%.

Several studies attempted to discern variables associated with the presence of OSAS. Three studies found an equal prevalence between males and females,^{16–18} and 2 studies found an increased prevalence in males.^{12,15} Two studies reported an increased risk in children of ethnic minorities,^{11,19} supporting older data.²⁰ Four studies found an increased risk in obese patients,^{12,17,21,22} but 3 studies did

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs or diagnostic studies in relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies		
C. Observational studies (case-control and cohort design)	Recommendation	
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation	
	Recommendation	

FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT, randomized controlled trial.

TABLE 2 Definitions and Recommendation Implications

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

TABLE 3 Results of Text-Mining of the Methods Section of 757 Papers

Term Used for Text-Mining	Percentage of Papers
Snore/snoring	58.3
Polysomnography	53.6
Diagnosis	53.4
Medical management	51.6
Survey/questionnaire	38.8
Psychological	37.0
Surgery/surgical	35.9
Treatment	32.1
Design	27.8
Obese/obesity	25.0
BMI	24.6
Randomize	20.2
Blinding	16.4
Sampling	11.7
Control group	8.8
Actigraphy	2.6
Mortality	0.5

TABLE 4 Types of Studies in the Literature Based on 350 Articles

Type of Study	Percentage
Descriptive study	33.7
Nonrandomized concurrent cohort series	32.0
Descriptive study + other	10.8
Nonrandomized historical cohort series	7.8
Randomized clinical trial	4.6
Retrospective	3.6
Case-control study	1.3
Prospective consecutive cohort series	1.3
Cross-sectional population-based survey	1.0
Nonrandomized historical cohort series + other	1.0
Randomized + other	1.0
Undetermined	1.0
Nonrandomized concurrent cohort series + other	0.7
Experimental study	0.3

not.^{15,16,23} Another study reported an increased risk of OSAS with increased waist circumference, a marker for obesity.¹¹ One study found an increased risk with nasal abnormalities,¹¹ 1 study found an increased risk with prematurity,¹⁹ and 2 studies found increased risk with adenotonsillar hypertrophy.^{12,22}

Multiple studies (levels II–IV) investigated the prevalence of HS, which is one of the most prominent manifestations of OSAS (Table 7). The presence of snoring was based on parental or personal questionnaires. Not all of the questionnaires used have been validated, and the data relied on subjective responses rather than objective clinical evaluations. The reported prevalence of HS varied widely, depending on the study and definition used, from 1.5% to 27.6%.

In summary, studies of OSAS and HS show varied prevalence rates, depending on the population studied, the methods used to measure breathing during sleep, and the definitions used for diagnosis. Nevertheless, the preponderance of evidence suggests a prevalence of OSAS in the range of 1% to 5%, making this a relatively common disease that would be encountered by most clinicians in primary practice.

Areas for Future Research

- Population-based studies on the gender and race distribution of OSAS among different age groups.

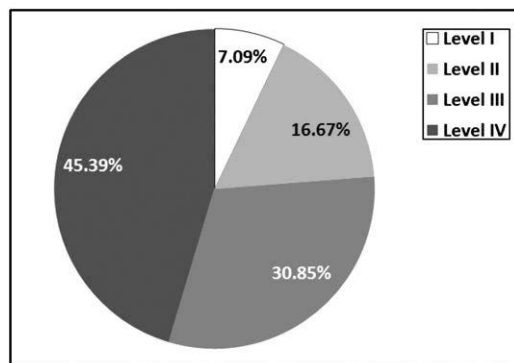
SEQUELAE OF OSAS

Neuropsychological and Cognitive Problems Associated With OSAS

Of the 350 articles related to this search over the last 10 years, 61 articles directly explored the relationship between SDB and cognitive or neuropsychological deficits. In total, 29 658 subjects were studied, including 2 level I studies^{24,25} with a total of 174 subjects and 5 level II studies.^{26–30} The diagnosis of SDB was based on clinical symptoms in 29 articles and on PSG in 32 articles.

Cognitive Deficits

All but 1 study (level IV)³¹ demonstrated deficits in cognition or neuropsychological function in association with symptoms, signs, or diagnosis of SDB. The 1 exception examined children who had mild OSAS over a wide age range and did not include behavioral assessments. In this study, the mean IQ in the OSAS population was significantly above the standard mean. Some^{32–34} but not all studies showed a correlation between the severity of obstructive apnea as measured on PSG and increasing neuropsychological morbidity. There are several reasons why correlations were not found for all studies. Standard PSG was developed to detect cardiorespiratory variations and may not be an adequate tool for detection of sleep changes that affect neuropsychological function. Another possibility is that any degree of SDB is associated with abnormal neuropsychological outcomes and might be affected variably by social, medical, environmental, or socioeconomic factors not measured by using PSG. This

**FIGURE 2**

Levels of evidence of articles used for this report.

TABLE 5 Prevalence of OSAS on the Basis of Laboratory PSG

Source	Year	No.	No. Undergoing PSG	Country	Age, y	OSASPrevalence	HSPrevalence	OSAS Criteria/Comments
Anuntasree et al ²⁰¹	2001	1005	8	Thailand	6–13	0.69%	8.5%	AHI ≥1
Anuntasree et al ²⁰²	2005	755	Unclear, possibly 10			1.3%	6.9% “most nights”	Note: 2 studies used same cohort
Beebe et al ²¹	2007	60 obese 22 control	All	United States	10–16.9	0% normal 13% obese		AHI >5 ↑ in obese
Bixler et al ¹¹	2009	5740	700	United States	5–12	1.2%		AHI ≥5 ↑ in obese ↑ in ↑ waist circumference ↑ with nasal abnormalities ↑ in minority race
Brunetti et al ²⁰³	2001	895	34 home monitoring	Italy	3–11	1%–1.8%	4.9%	AHI >3
Brunetti et al ²³	2010		12 PSG				5.4% “always”	Not ↑ in obese; Note: 2 studies used same cohort
Li et al ¹⁷²	2010	6447	619	China	5–13	4.8%	7.2% “frequently”	Using ICSD-II criteria 4.8% ↑ in boys ↑ in obese
Li et al ¹²	2010							↑ in tonsil size AHI >1 AHI >5
Ng et al ²⁰⁴	2002	200	16	Hong Kong	6.4 ± 4	1%	14.5%	Used AHI >3 Boys = girls
O'Brien et al ¹³	2003	5728	110	United States	5–7	5.7%	11.7% “frequent and loud”	Not ↑ in obese OAI ≥1 or RDI ≥5
Sogut et al ¹⁶	2005	1198 total	28	Turkey	3–11	0.9%–1.3%	3.3% >3 times/week	Boys = girls ↑ in obese
Wing et al ¹⁷	2003	46 obese, 44 control	All	China	7–15	2.3%–4.5% control; 26% to 32.6% obese		OAI ≥1 or RDI ≥5 Boys = girls ↑ in obese
Xu et al ²²	2008	99 obese, 99 control	All	China	Elementary school	0 if not obese and no ATH		AHI >5 or OAI >1 ↑ obese ↑ in ATH

ATH, adenotonsillar hypertrophy; ICSD, International Classification of Sleep Disorders; OAI, obstructive apnea index.

possibility is confirmed by a recent level I study showing that obesity, OSAS, and neurocognitive outcomes are all interdependent.³⁵ Furthermore, most studies were not controlled for socioeconomic status (SES), which is important because SES strongly affects the results of neurocognitive testing and because OSAS is associated with low SES.³⁶ Although some studies have shown abnormalities in snorers compared with nonsnoring controls, in many of these studies, data in snorers still fell within the normal range.²⁴ In addition, cutoffs for OSAS used in some studies resulted in a blurring of boundaries between the OSAS and snoring groups. For example, Chervin et al used an obstructive apnea index cutoff of only ≥0.5/hour to define OSAS, and the mean apnea index for the OSAS group was 2.9 events/hour, indicating that the study group had mild OSAS, which was not that different from the snorers.^{37,38} A study with a wider spectrum of severity may have attained different results. Finally, most studies have not controlled for obesity, which has been associated with neurobehavioral and cognitive abnormalities.

Although most studies simply compared groups, others have looked at the correlation between polysomnographic indices and neurocognitive/behavioral outcomes and have shown a correlation between different polysomnographic factors and cognitive outcomes, behavioral outcomes, and sleepiness.^{32–34,39}

Cognitive deficits associated with pediatric SDB include general intelligence level as well as processes measured by using IQ subtests (Table 8). Specific functions objectively measured by using neuropsychological assessments and included in the research studies include:

- Learning, memory, and visuospatial skills

TABLE 6 Prevalence of OSAS on the Basis of Ambulatory Monitoring

Source	Year	No.	No. Undergoing Ambulatory Monitoring	Country	Age, y	OSAS Prevalence, %	HS Prevalence	OSAS Criteria and Comments
Castronovo et al ¹⁴	2003	595	265	Italy	3–6	12	34.5% “Often” or “Always”	OAI ≥ 5
Goodwin et al ¹⁵	2005	480	All	United States	6–11	24	10.5% “Frequently”	RDI ≥ 1 $\uparrow$ in male Not $\uparrow$ in obese
Hultcrantz and Löfstrand Tideström ²⁰⁵	2009	393	26	Sweden	12	0.8	6.9% “Regularly”	AHI ≥ 1 and/ or OAI ≥ 1
Rosen et al ¹⁹	2003	850	All	United States	8–11	2.2		AHI ≥ 5 or OAI ≥ 1 $\uparrow$ in AA $\uparrow$ in premature infants
Sánchez-Armengol et al ¹⁸	2001	101	All	Spain	12–16	1.9	14.8% “Often”	Based on RDI ≥ 10 and snoring, witnessed apneas, and/or excessive daytime sleepiness. Girls = boys AHI ≥ 1
Urschitz et al ²⁰⁶	2010	1144	183	Germany	7.3–12.4	2.8		

OAI, obstructive apnea index; AA, African American.

TABLE 7 Prevalence of HS

Source	Year	No.	Country	Age, y	HS Prevalence, %	HS Criteria
Akçay et al ²⁰⁷	2006	1784	Turkey	4–17	4.1	“Often”
Alexopoulos et al ²⁰⁸	2006	1821	Greece	5–14	7.4	>3 times/wk
Archbold et al ²⁰⁹	2002	1038	United States	2–13.9	17.1	“More than half of the time”
Bidad et al ¹⁶⁷	2006	2900	Iran	11–17	7.9	≥ 3 times/wk
Chng et al ²¹⁰	2004	11 114	Singapore	4–7	6.0	>3 times/wk
Corbo et al ¹⁶⁶	2001	2209	Italy	10–15	5.6	“Often”
Ersu et al ²¹¹	2004	2147	Turkey	5–13	7.0	“Often”
Goodwin et al ²¹²	2003	1494	United States	4–11	10.5	“Snoring frequently or almost always”
Gottlieb et al ²¹³	2003	3019	United States	5	12	≥ 3 times/week
Johnson and Roth ⁴⁵	2006	1014	United States	13–16	6	“Every or nearly every night”
Kuehni et al ²¹⁴	2008	6811	United Kingdom	1–4	7.9	“Almost always”
Liu et al ²¹⁵	2005	517 in China 494 in USA	China United States	Grade school	1.5 (China) 9.9 (United States)	Snoring loudly 5–7 times/wk
Liu et al ²¹⁵	2005	5979	China	2–12	5.6	“Frequent”
Löfstrand-Tideström and Hultcrantz ²¹⁶	2007	509	Sweden	4–6	5.3–6.9	“Snoring every night”
Lu et al ²¹⁷	2003	974	Australia	2–5	10.5	≥ 4 times/week
Montgomery-Downs et al ⁴⁴	2003	1010	United States	Preschool	HS and risk of SDB, 22	≥ 3 times/week
Nelson and Kulnis ²¹⁸	2001	405	United States	6–17	17	“Often”
Ng et al ²¹⁹	2005	3047	China	6–12	10.9	6–7 times/wk
Perez-Chada et al ²²⁰	2007	2210	Argentina	9–17	9	“Frequent”
Petry et al ²²¹	2008	998	Brazil	9–14	27.6	“Frequently” or “always”
Sahin et al ²²²	2009	1164	Turkey	7–13	3.5	“Frequently” or “almost every day”
Sogut et al ¹⁶	2005	1030	Turkey	12–17	4.0	“Often” or “always”
Tafur et al ²²³	2009	806	Ecuador	6–12	15.1	“Often” or “always”
Urschitz et al ¹⁶⁴	2004	1144	Germany	Primary school	9.6	“Always” or “frequently”
Zhang et al ²²⁴	2004	996	Australia	4–12	15.2	>4 times/wk

- Language, verbal fluency, and phonological skills
- Concept formation, analytic thinking, and verbal and nonverbal comprehension

- School performance and mathematical abilities
- Executive functions
Executive functions were measured by using both objective testing and parent

questionnaires. Executive functions are a network of skills and higher order functions that control and regulate other cognitive processes. These skills require mental flexibility, impulse control,

TABLE 8 Cognitive Deficits Associated With Pediatric SDB

Type of Deficit	Source	Level	No.	Findings/Comments
Cognition, general intelligence	Beebe et al ²²⁵	IV	895	Deficits of general intelligence, sensorimotor integration by objective measurement; behavioral abnormalities included as well
	Blunden et al ²²⁶			
	Kaemingk et al ³³			
	Kennedy et al ³⁴			
	Kurnatowski et al ²²⁷			
	Carvalho et al ²²⁸	III	1332	Objective measures of general intelligence, verbal skills affected by SDB
	Montgomery-Downs et al ⁵⁰			
	Suratt et al ⁴³			
	Friedman et al ²⁶	II	473	General intelligence, executive function, language all affected by SDB and measured objectively
	Halbower et al ²⁸			
	O'Brien et al ²⁹			
Poor school performance	Kohler et al ³⁰	I	174	General conceptual ability, verbal and nonverbal reasoning, vocabulary affected by SDB (and time in bed ²⁵)
	O'Brien et al ²⁴			
	Suratt et al ²⁵			
	Chervin et al ⁴²	IV	11 110	Academic achievement measured either by parent or school grades
	Johnson and Roth ⁴⁵			
	Kaemingk et al ³³			
	Ng et al ²¹⁹			
	Perez-Chada et al ²²⁰			
	Shin et al ⁴⁷			
	Urschitz et al ²²⁹	III	1010	Snoring associates with ethnicity, school performance in SES-challenged preschool-aged children
	Montgomery-Downs et al ⁴⁴			
Executive function	Beebe et al ²²⁵	IV	179	Mental flexibility, impulse control
	LeBourgeois et al ²³⁰			
	Karpinski et al ²³¹			
	Halbower et al ²⁸	II	123	Response preparation, working memory, fluid and quantitative reasoning; objective testing performed by blinded tester
	Kohler et al ³⁰			
Learning, information processing, memory, visuospatial skills	Goodwin et al ²¹²	IV	1838	Objective testing performed in all but Goodwin et al ²¹² (questionnaire)
	Hamasaki Uema et al ²³²			
	Kaemingk et al ³³			
	Kennedy et al ³⁴			
	Kurnatowski et al ²²⁷			
	O'Brien et al ²³³	II	112	Race ²⁸ and BMI may play an additive role in inflammation ⁴⁶ and cognitive dysfunction in SDB
	Spruyt et al ²³⁴			
	Giordani et al ³⁸			
	Halbower et al ²⁸			
	Tauman et al ⁴⁶			
Language/verbal skills	O'Brien et al ²⁴	I	118	Primary snoring without gas exchange abnormalities associates with significantly lower learning and memory
	Kurnatowski et al ²²⁷	IV	3304	Deficits of language or verbal skills in SDB
	O'Brien et al ²³³			
	Perez-Chada et al ²²⁰			
	Honaker et al ²³⁵			
	Lundeborg et al ⁵¹			
	Suratt et al ⁴³	III	114	Race and time in bed may contribute to abnormal language associated with SDB
	Montgomery-Downs et al ⁵⁰			
	O'Brien et al ²⁴			
	Suratt et al ²⁵	I	118	Primary snoring without gas exchange abnormalities associated with significantly lower verbal skills; deficits of language or verbal skills in SDB
Attention	Beebe et al ²²⁵	IV	6411	Objective testing performed for attention except in refs 32,33,213,229, and 236 in which parent or teacher questionnaires were used
	Chervin et al ²³⁶			
	Galland et al ²³⁷			
	Gottlieb et al ²¹³			
	Hamasaki Uema et al ²³²			
	Kaemingk et al ³³	I	105	Visual and auditory attention
	Li et al ²³⁸			
	Mulvaney et al ³²			
	Urschitz et al ²²⁹			
	Chervin et al ³⁷			
	O'Brien et al ²⁴	I	118	Visual and auditory attention

and working memory. Executive functions are required for optimal school performance and are acquired through adolescence in developing children.

Behavioral Abnormalities

The investigations on the cognitive effects of SDB in the 61 studies often included measures of neurobehavioral outcomes (Table 9). Hyperactivity was the most commonly studied and/or reported behavioral abnormality associated with SDB. It was reported as a frequent symptom of SDB in younger children, and in fact, in 1 study, snoring was found to be strongly predictive of a future diagnosis of hyperactivity over the long-term (level IV).⁴⁰ Attention-deficit/hyperactivity disorder (ADHD) or ADHD symptoms, hypersomnolence, somatization, depression, atypicality, aggression, and abnormal social behaviors were the other most frequently reported behavioral abnormalities associated with SDB in children. Most behavioral difficulties were defined by using parent or teacher questionnaires in unblinded level IV studies.

Sleepiness

Two studies (levels I–II) have shown a relationship between polysomnographic measures and objective measurement of daytime sleepiness on multiple sleep latency testing.^{27,39}

Exacerbation of Neuropsychological Deficits by Other Factors Underlying Childhood SDB

Abnormal behavioral alterations associated with SDB might be modified or directly caused by other sleep disorders, such as coexistent periodic limb movement disorder.⁴¹ In children with SDB displaying deficits of cognition, school performance, or behavioral functioning, there may be additive roles played by race,^{28,42–44} decreased time in bed,^{25,43} and low SES,^{28,42,44,45} at least in part because of

the association between obesity and low SES.⁴² Markers of inflammation and increased cardiovascular risk may point to 1 mechanism related to decreased cognitive function associated with OSAS,⁴⁶ seen also in children who are obese. BMI correlated with abnormal cognitive function in pediatric SDB,^{42,45,47} although OSAS was found to be an independent risk factor for cognitive deficits. Finally, in 2 studies examining brain function, neuronal injury of the brain²⁸ and altered cerebral blood flow⁴⁸ were found in children who had SDB compared with normal controls and were associated with behavior and cognitive problems. These findings indicate the possibility of preexisting medical problems causing the development of OSAS or, alternatively, OSAS causing brain injury. Therefore, studies showing improved cognition and behavior after treatment of SDB are 1 key in the determination of causality (see the following discussion).

Neuropsychological and Cognitive Deficits in Children Who Have SDB Improve After Treatment

In the previous guideline, there were few before-and-after treatment studies of pediatric SDB focusing on objectively measured cognitive problems. In the last 10 years, 19 studies have examined changes in behavior and/or cognition after surgical treatment of OSAS. The majority of investigations demonstrated agreement about post-treatment improvement of behavior, quality of life (QoL), hyperactivity, ADHD, and impulsivity (Table 10). The exception was 1 study of exercise treatment (level IV),⁴⁹ in which snoring improved in obese children but behavior and sleepiness did not. Most studies used subjective questionnaire reports. Excessive daytime sleepiness improved in 1 study that measured this factor, as did depression, sleep quality, and aggressive behavior. Since

publication of the last guideline, 3 additional studies have demonstrated improved cognitive function (by using objective measurement) after treatment of OSAS, including measures of general intelligence, attention, memory, and analytic thinking, including level II,²⁶ level III,⁵⁰ and level IV³⁷ studies (Table 10). Of concern, however, is that some recent articles suggest that certain deficits of cognition measured by using objective testing may not improve to a large extent after treatment of childhood OSAS. Language, IQ, and executive function did not improve significantly in a well-designed, controlled study of 92 children (level II).³⁰ General intelligence in at-risk populations improved in 1 study (level III),⁵⁰ but phonologic processes and verbal fluency did not improve to normal (level III⁵⁰ and level IV⁵¹). QoL increases after treatment.^{37,52–58} Three studies demonstrated long-term (≥ 1 year) behavioral or QoL improvements.^{37,52,53} The majority of these studies suggest that in developing children who are dependent on executive function, cognition, and behavioral skills for daily function and school performance, treatment of childhood SDB has benefits.

Conclusion

In summary, these studies suggest that, in developing children, early diagnosis and treatment of pediatric OSAS may improve a child's long-term cognitive and social potential and school performance. These findings imply that the earlier a child is treated for OSAS, the higher the trajectory for academic and, therefore, economic success, but research is needed to support that implication. There is demonstrated benefit in terms of behavior, attention, and social interactions, as well as likely improvement in cognitive abilities with

TABLE 9 Behavioral Abnormalities Associated With Pediatric SDB

Type of Deficit	Source	Level	No.	Test Conditions				
Hyperactivity and/or ADHD	Chervin et al ²³⁶	IV	8101	Hyperactivity generally measured by using parent questionnaire				
	Chervin et al ⁴⁰							
	Galland et al ²³⁷							
	Golan et al ²³⁹							
	Gottlieb et al ²¹³							
	Johnson and Roth ⁴⁵							
	LeBourgeois et al ²³⁰							
	Mitchell and Kelly ²⁴⁰							
	Owens et al ¹⁸⁹							
	Roemmich et al ¹⁹¹							
	Urschitz et al ²²⁹							
Montgomery-Downs et al ⁴⁴	III	1010	Survey data					
Chervin et al ³⁷	I	105	ADHD assessed by using psychiatric interview and validated instrument					
Somatization, depression	Galland et al ²³⁷	IV	205					
	Mitchell and Kelly ²⁴⁰							
	Mitchell and Kelly ²⁴¹							
	Rudnick and Mitchell ²⁴²							
	Suratt et al ⁴³				III	114		
Behavior problems, general	O'Brien et al ²⁴	I	118	Behavior generally measured by using parent questionnaire				
	Goldstein et al ⁵⁵	IV	1946					
	Goldstein et al ²⁴³							
	Hogan et al ⁴⁸							
	Li et al ²³⁸							
	Mitchell and Kelly ²⁴¹							
	Mulvaney et al ³²							
	Owens et al ¹⁸⁹							
	Roemmich et al ¹⁹¹							
	Rosen et al ²⁴⁴							
	Rudnick and Mitchell ²⁴²							
	Tran et al ⁵⁸							
	Wei et al ²⁴⁵							
	Aggression, oppositional and social problems				Chervin et al ²⁴⁶	IV	4407	
					Gottlieb et al ²¹³			
Galland et al ²³⁷								
Mitchell and Kelly ²⁴⁰								
Mulvaney et al ³²								
Excessive daytime sleepiness	O'Brien et al ²⁴	I	118	Sleepiness measured by using questionnaire				
	Goodwin et al ²¹²	IV	9729					
	Perez-Chada et al ²²⁰							
	Shin et al ⁴⁷							
	Urschitz et al ²²⁹							
	Johnson and Roth ⁴⁵							
	Gozal et al ²⁷				II	92		
	Chervin et al ³⁷				I	105		
Anxiety	O'Brien et al ²⁴			I	118	Sleepiness measured objectively by multiple sleep latency testing on PSG		
				Sleepiness measured objectively by multiple sleep latency testing on PSG				

the treatment of pediatric OSAS. However, more long-term studies are needed. The risks of treatment depend on the type of treatment but include risk of surgery, risk of medication, nonadherence to therapy, and cost.

The risks of not treating children who have OSAS include potentially affecting the child's trajectory of developmental gains dependent on intelligence, executive function, and proper social interactions, ultimately lowering lifetime

academic and social achievements. Therefore, the benefit of treating childhood OSAS outweighs the risk where treatment is feasible.

Areas for Future Research

- Further research is required to determine which domains of cognitive function will improve with treatment of OSAS. Reversibility of cognitive deficits associated with OSAS must be adjusted for the confounding effects of age, length of symptoms, SES, BMI, sleep duration, environment, and race and ethnicity.

Cardiovascular Effects of OSAS

A total of 24 studies related to cardiovascular effects of OSAS in childhood were identified since the last review. The levels of evidence were III and IV.

In a retrospective, level IV study of 271 clinical cases, only 1 child, who had congenital heart disease, had signs of cardiac failure preoperatively, and other cases had no evidence of left or right ventricular hypertrophy.⁵⁹ However, studies using more sophisticated, prospective techniques have found subclinical evidence of cardiac dysfunction. These studies are described in Table 11. Although postoperative adenotonsillectomy (AT) cardiac complications are rare (level IV),⁵⁹ left and right ventricular hypertrophy is significantly associated with postoperative respiratory complications (level III),⁶⁰ supporting the recommendation in the current and the previous guidelines that children who have cardiac abnormalities be monitored as inpatients postoperatively.

Blood pressure (BP) has also been shown to be affected by OSAS in children. There were 9 recent level III or IV studies, most of which showed a correlation between the presence/

TABLE 10 Cognitive, Behavioral, and QoL Abnormalities Improved After Treatment of Pediatric SDB

Deficit Measured	Source	Level	No.	Abnormalities Improved After SDB Treatment
Cognition/IQ	Chervin et al ³⁷	I	105	Attention measured on continuous performance test improved significantly after treatment
	Montgomery-Downs et al ⁵⁰	III	38	General conceptual ability improved (verbal fluency did not improve)
	Friedman et al ²⁶	II	59	Auditory-visual integration, auditory-motor memory, short-term memory, retention, analytic thinking, IQ/mental processing, attention all improved
Hyperactivity and/or ADHD	Galland et al ²³⁷	IV	247	Hyperactivity and/or diagnosis of ADHD improved
	Li et al ²³⁸			
	Mitchell and Kelly ²⁴⁰			
	Mitchell and Kelly ²⁴¹			
	Roemmich et al ¹⁹¹			
Somatization, depression	Chervin et al ³⁷	IV	153	Long-term improvement in hyperactivity and/or somatization
	Galland et al ²³⁷			
	Mitchell and Kelly ²⁴⁰			
	Mitchell and Kelly ²⁴¹			
Behavior problems, general	Goldstein et al ⁵⁵	IV	450	All showed behavior improvement except Davis et al ⁴⁹ Long-term behavior improvement in Mitchell et al ⁵³
	Goldstein et al ²⁴³			
	Hogan et al ⁴⁸			
	Li et al ²³⁸			
	Roemmich et al ¹⁹¹			
	Tran et al ⁵⁸			
	Wei et al ²⁴⁵			
	Mitchell et al ⁵³			
	Davis et al ⁴⁹			
Aggression, oppositional, and social problems	Galland et al ²³⁷	IV	113	Improvement in abnormal social behavior and aggression
Excessive daytime sleepiness	Mitchell and Kelly ²⁴⁰			
	Chervin et al ³⁷	I	105	Sleepiness improved by 1 min, as measured by using multiple sleep latency testing on PSG
QoL	Colen et al ⁵²	IV	787	Includes disease-specific and emotional QoL ⁵⁸ Long-term improvements ≥ 1 y ^{52,53}
	Constantin et al ⁵⁴			
	Goldstein et al ⁵⁵			
	Sohn et al ⁵⁶			
	Silva and Leite ⁵⁷			
	Tran et al ⁵⁸			
Sleep quality	Chervin et al ³⁷	I	105	Long-term improvements at 1 y
	Constantin et al ⁵⁴	IV	590	Improved in both studies
	Wei et al ²⁴⁵			

severity of OSAS and indices of elevated BP (Table 12).

In a study by Kaditis et al,⁶¹ overnight changes in brain natriuretic peptide levels were large in children who had an apnea hypopnea index (AHI) ≥ 5 /hour when compared with those with milder OSAS and with controls (level III). This finding suggests the presence of nocturnal cardiac strain in children who have moderate to severe OSAS.

Two studies evaluated brain oxygenation and cerebral artery blood flow. Khadra et al⁶² reported that male gender, arousal index, and amount of non-rapid eye movement sleep were associated with diminished cerebral oxygenation, whereas increasing mean arterial pressure, age, oxygen saturation (SpO₂), and amount of rapid eye movement sleep were associated with augmented cerebral oxygenation (level III). Hogan et al⁴⁸ found

a decrease in middle cerebral artery velocity postoperatively in patients treated for OSAS, whereas control subjects showed a slight increase over time (level IV).

Three studies evaluated autonomic variability in children who have OSAS. Constantin et al⁶³ reported resolution of tachycardia and diminished pulse rate variability after AT in children who had OSAS (diagnosis of OSAS based on oximetry plus questionnaire data) (level IV). Deng et al⁶⁴ studied heart rate variability and determined that heart rate chaos was modulated by OSAS as well as by sleep state (level IV). In a study of 28 children who had OSAS, O'Brien and Gozal⁶⁵ found evidence of altered autonomic nervous system regulation, as evidenced by increased sympathetic vascular reactivity, during wakefulness in these children (level III). These studies all suggest that OSAS places stress on the autonomic system.

In summary, a large number of studies, albeit primarily level III, found that cardiac changes occur in the presence of OSAS, with an effect on both the right and left ventricles. OSAS in childhood also has an effect on both systolic and diastolic BP. In addition, several studies suggest that childhood OSAS can affect autonomic regulation, brain oxygenation, and cerebral blood flow. These studies suggest that childhood OSAS may jeopardize long-term cardiovascular health.⁶⁶

The association between left ventricular remodeling and 24-hour BP highlighted the role of SDB in increasing cardiovascular morbidity.

Areas for Future Research

- How reversible, after treatment, are cardiovascular changes in children who have OSAS?
- What are the long-term effects of OSAS on the cardiovascular system?

TABLE 11 Structural and Functional Cardiac Abnormalities in Children Who Have OSAS

Source	Level	No.	Findings
Left-sided cardiac dysfunction			
Amin et al ²⁴⁷	III	28 OSAS 19 PS	Abnormalities of LV geometry in 39% of OSAS vs 15% of PS; OSAS associated with increased LV mass
Amin et al ²⁴⁸	III	48 OSAS 15 PS	Dose-dependent decrease in LV diastolic function with increased severity of SDB
Right-sided cardiac dysfunction			
Duman et al ²⁴⁹	III	21 children, ATH; 21 controls	Higher RV myocardial performance index in patient with adenotonsillar hypertrophy than in controls; this decreased significantly after AT, along with symptoms of OSAS
Ugur et al ²⁵⁰	III	29 OSAS 26 PS	Improved RV diastolic function after AT, with postoperative values similar to controls
Biventricular cardiac dysfunction			
James et al ⁵⁹	IV	271	Case review of ECG and chest radiography results found only 1 case of cardiac failure, which occurred in a child who had congenital heart disease; most other cases showed no abnormalities
Weber et al ²⁵¹	III	30 OSAS 10 controls	Increased RV diameter and area during both systole and diastole; reduced LV diastolic diameter and ejection fraction

ATH, adenotonsillar hypertrophy; LV, left ventricle; PS, primary snoring; RV, right ventricle.

TABLE 12 BP in Children Who Have OSAS

Source	Level	No.	Findings
Kohyama et al ¹⁷⁵	IV	23 suspected OSAS	REM diastolic BP index correlated with AHI Age, BMI, and AHI were significant predictors of systolic BP index during REM
Kwok et al ⁶⁶	III	30 PS	Children with PS had increased daytime BP and reduced arterial distensibility
Leung et al ²⁵²	III	96 suspected OSAS	Children with a higher AHI had higher wake systolic BP and sleep systolic and diastolic BP BMI, age, and desaturation index contributed to elevation of the diastolic BP during sleep, but only BMI contributed to the wake and sleeping systolic BP
Guilleminault et al ²⁵³	III	Retrospective component: 301 suspected OSAS Prospective component: 78 OSAS	Some children who have OSAS have orthostatic hypotension
Li et al ¹⁷⁶	III	306 community sample	OSAS was associated with elevated daytime and nocturnal BP
Amin et al ¹⁷⁷	III	140 suspected OSAS	OSAS associated with an increase in morning BP surge, BP load, and 24-h BP. BP parameters predicted changes in left ventricular wall thickness
Amin et al ²⁵⁴	III	39 OSAS 21 PS	OSAS was associated with 24-h BP dysregulation AHI, SpO ₂ , and arousal contribute to abnormal BP control independent of obesity
Enright et al ²⁵⁵	III	239 community sample	Obesity, sleep efficiency, and RDI were independently associated with elevated systolic BP
Kaditis et al ¹⁷⁴	IV	760 community sample	No difference in morning BP between habitual snorers and nonhabitual snorers

PS, primary snoring; REM, rapid eye movement.

Growth

The section on obesity contains a detailed review of obesity and OSAS,

including the relationship between OSAS and the metabolic syndrome. The previous guideline documented many

studies showing a relationship between OSAS and growth, and an increase in growth parameters after treatment of SDB by AT; this outcome has been confirmed by a number of more recent studies (as discussed in the recent meta-analysis by Bonuck et al⁶⁷). In a confirmation of previous reports,^{68,69} Selimoğlu et al⁷⁰ found a decreased level of serum insulin-like growth factor-I in children who have OSAS, which increased significantly 6 months after AT (level III).

Inflammation

Since the publication of the 2002 AAP guideline, there has been growing research on the role of OSAS in systemic inflammation. It has been postulated that OSAS results in intermittent hypoxemia, leading to production of reactive oxygen species. In addition, the hypoxemia and arousals from sleep lead to sympathetic activation. These factors may trigger inflammation or exacerbate obesity-related inflammation. However, the data on OSAS and markers of systemic inflammation in children are scarce and contradictory.

Eight studies (level II–III) measured levels of C-reactive protein (CRP) in children who had OSAS. Four studies (including 2 from the same center) showed no relationship between CRP and OSAS,^{71–74} whereas 4 studies (2 from the same center) did show a relationship.^{46,75–77} Part of the discrepancy between studies may be attributable to the varying proportions of obese subjects (because obesity is associated with high CRP levels) and varied age of subjects and definitions of OSAS in the different studies. Some studies controlled for obesity and degree of OSAS, whereas others did not. The studies showing a positive relationship indicated that OSAS was associated with elevated

CRP levels only above a certain threshold of severity. Thus, the relationship between OSAS and CRP seems to be complex and is affected by obesity and severity of OSAS.

A few level II and III studies have evaluated other circulating markers of inflammation in children who have OSAS. Two studies showed no difference in circulating intercellular adhesion molecule-1 between patients with OSAS and controls.^{71,73} A single study found elevated p-selectin (a measure of platelet activation) in children who had OSAS compared with controls.⁷³ A single study showed elevated levels of interferon- γ in children who had OSAS.⁷⁴ One study showed increased interleukin (IL)-6 and lower IL-10 in those with OSAS,⁷⁸ whereas another study did not.⁷⁴ Another study reported no difference in cytokines IL-1 β , IL-2, IL-4, IL-8, IL-12, and granulocyte macrophage colony-stimulating factor levels between children who had OSAS and controls.⁷⁴ Data on tumor necrosis factor- α are conflicting,^{74,79} and differences in levels may be related to tumor necrosis factor- α gene polymorphisms.⁸⁰

A pathology-based study found increased glucocorticoid receptors in adenotonsillar tissue from children who had OSAS compared with tissue from children who experienced chronic throat infections (level III)⁸¹; another study from the same group found elevated leukotriene receptors (level IV).⁸² These findings provide a theoretical construct for the potential utility of antiinflammatory drugs as treatment of children who have OSAS, although possibly not for those who have already undergone AT.

In summary, the data on CRP are conflicting, but it may be that CRP levels increase above a certain threshold of severity of OSAS. Further research involving large samples of subjects who have varying degrees of OSAS severity,

with results controlled for BMI and age, are needed. There are too few data on other circulating markers of systemic inflammation to enable any recommendations.

Areas for Future Research

- Larger studies, stratified for the severity of OSAS and controlled for obesity, are required to determine whether OSAS is associated with systemic inflammation. If so, what are the long-term sequelae of this inflammation? Are inflammatory biomarkers potential good outcome measurements for OSAS treatment studies? Do they correlate with clinical outcomes or long-term prognosis?

METHODS OF DIAGNOSIS

The previous guideline discussed the diagnosis of OSAS in great detail. On the basis of published evidence at the time, it was concluded that the positive and predictive value of history and physical examination for the diagnosis of OSAS was 65% and 46%, respectively; that is, no better than chance. It was therefore recommended that objective testing be used for the diagnosis of OSAS. An evaluation of the literature regarding nocturnal pulse oximetry, video recording, nap PSG, and ambulatory PSG suggested that these methods tended to be helpful if results were positive but had a poor predictive value if results were negative. Thus, children who had negative study results should be referred for more comprehensive testing. These recommendations were based on only a few studies, most of which had a low level of evidence. Furthermore, it was recognized that these techniques were of limited use in evaluating the severity of OSAS (which is important in determining management, such as whether outpatient surgery can be performed safely). In

addition, the cost efficacy of these screening techniques had not been evaluated and would depend, in part, on how many patients eventually required full PSG. Since the publication of the initial guideline, there have been a number of new studies, but few are level I or II. Because few of the studies cited here included data that would enable calculation of overall sensitivity and specificity or positive and negative predictive values, an overall table could not be provided. For this section, PSG was considered the gold standard for diagnosis of OSAS.

Utility of History Alone for the Diagnosis of OSAS

Several level IV studies evaluated the use of history alone for the diagnosis of OSAS. Preutthipan et al⁸³ found overall poor sensitivity and specificity when evaluating various historical factors. The Pediatric Sleep Questionnaire published by Chervin et al⁸⁴ performed slightly better than other published questionnaires, with a sensitivity of 0.85 and a specificity of 0.87 by using a set cutoff. A follow-up study by the same group showed a sensitivity of 78% and a specificity of 72% for PSG-defined OSAS.⁸⁵ However, this is still a relatively low sensitivity and specificity for clinical purposes. By using this instrument, the same group also found that negative answers to only 2 questions on the Pediatric Sleep Questionnaire were helpful in identifying patients who had normal PSG results.⁸⁶ Taken together, the overall performance of questionnaire tools seems to support their use more as a screening tool than as a diagnostic tool, such that a negative score would be unlikely to mislabel a child with OSAS as being healthy, but a positive score would be unlikely to accurately diagnose a particular child with certainty.

Utility of Clinical Evaluation for the Diagnosis of OSAS

Similar to the data presented in the previous guideline, most studies found that clinical evaluation was not predictive of OSAS on PSG. Godwin et al¹⁵ performed a large ($N = 480$), population-based study of 6- to 11-year-old children. The study included use of a standardized history, some clinical parameters, and ambulatory, full PSG (level II). They concluded that the sensitivity of any individual or combined clinical symptoms was poor. Certain parameters, such as snoring, excessive daytime sleepiness, and learning problems, had a high specificity.

In a level III study, van Someren et al⁸⁷ compared history and clinical examination by a pediatrician or otolaryngologist with abbreviated PSG (video recording, oximetry, and measurement of snoring). Both the sensitivity and specificity of the clinician's impression of moderate/severe OSAS were low (59% and 73%, respectively). In a similar number of cases, the clinicians underestimated (17%) and overestimated (16%) study results.

In a level III study, it was shown that waist circumference z score had a statistically significant but clinically poor correlation with symptoms of OSAS ($R = 0.32$, $P = .006$); BMI z score did not correlate with symptoms.⁸⁸

Radiologic Studies

Several studies, all level III or IV, evaluated the utility of radiologic examinations in addition to clinical factors in establishing the diagnosis of OSAS (Table 13). Overall, these studies showed that the presence of airway narrowing on a lateral neck radiograph increased the probability of predicting OSAS on PSG. Cephalometric studies tended to show a small mandible in patients who had OSAS

compared with controls, although a study using an MRI did not confirm this.⁸⁹ None of the cephalometric studies provided sensitivity and specificity or positive and negative predictive values. Table 13 simplifies the cephalometric findings for the purpose of presentation. A level I study indicated that acoustic pharyngometry may be a useful screening technique for OSAS in older children, but approximately one-half of the children could not cooperate well with the testing.⁹⁰ One uncontrolled study (level IV) showed that nasal resistance, as measured by using rhinometry, had a high sensitivity and specificity for predicting polysomnographic OSAS.⁹¹ This technique warrants further study and validation.

Snoring Evaluation

Two level IV studies found a weak association between objective snoring characteristics and the presence/severity of OSAS that was insufficient to assist in clinical diagnosis.^{92,93}

Cardiovascular Parameters

Studies have evaluated the utility of screening tests based on heart rate or other vascular factors in predicting OSAS (Table 14). These studies ranged from studies of pulse rate alone to more sophisticated (and, hence, more expensive or time-consuming) studies, such as analyses of heart rate variability, pulse transit time, and peripheral arterial tonometry. Studies were level II through IV. Overall, the studies found changes in cardiovascular variables in children who had OSAS but with varying sensitivities and specificities. Thus, some of these measures may potentially be useful screening tests in the future if combined with other modalities that would increase the sensitivity and specificity but cannot

be recommended for clinical use at this point.

Nocturnal Oximetry

The previous AAP guideline, on the basis of a single study by Brouillette et al,⁹⁴ indicated that nocturnal pulse oximetry could provide an accurate screen for OSAS if the result was positive but that full PSG was needed if the oximetry result was negative. A need for further research in this area was indicated. Four additional studies were identified for the current report. Two of these did not compare oximetry versus PSG and therefore will not be discussed further.^{95,96}

A follow-up study (level II) from the same group as the previous report by Brouillette et al⁹⁴ used overnight oximetry, primarily obtained in the home, to develop a scoring algorithm.⁹⁷ The subjects' median age was 4 years. The oximetry score correlated with the AHI obtained from PSG as well as with the presence of postoperative complications. However, the positive predictive value of oximetry for major postoperative respiratory compromise was only 13%. Of note, 80% of the 223 children had normal, inconclusive, or technically unsatisfactory oximetry results and were therefore referred for either repeat oximetry or PSG. In contrast, Kirk et al⁹⁸ compared overnight home oximetry (by using a system with an automated oximetry analysis algorithm that provided a desaturation index) with laboratory PSG in 58 children aged ≥ 4 years who had suspected OSAS (level III). They found poor agreement between the desaturation index on the basis of oximetry and the PSG-determined AHI. The sensitivity of oximetry for the identification of moderate OSAS (AHI >5 /hour) was 67%, and specificity was 60%. The oximetry algorithm tended to overestimate the AHI at low levels and underestimate at high

TABLE 13 Relationship Between Airway Measurements and OSAS

Clinical Evaluation	Sleep Evaluation	Airway Evaluation	Source	Level	No.	Findings
Standardized history, clinical examination	PSG	Lateral neck radiography	Xu et al ²⁵⁶	IV	50	Combinations of different predictor variables resulted in positive and negative predictor values ranging from 70% to 80%
Clinical examination	PSG	Lateral neck radiography	Jain and Sahni ²⁵⁷	IV	40	Degree of OSAS correlated with adenoid size on radiography but not with tonsillar size on clinical examination
Clinical examination	PSG	Lateral neck radiography	Li et al ²⁵⁸	IV	35	Tonsillar-pharyngeal ratio on radiography correlated with AHI but not clinical tonsil size. Clinical tonsil size did not correlate with AHI. For a ratio of 0.479, the sensitivity and specificity in predicting moderately severe OSAS (AHI >10/h) was 96% and 82%, respectively
NA	PSG	Cephalometry	Kawashima et al ²⁵⁹	III	15 OSAS 30 controls	Evidence of retrognathia in OSAS group
Clinical examination	Ambulatory abbreviated recordings	Cephalometry	Kawashima et al ²⁶⁰	III	38 OSAS 31 controls	OSAS: retrognathia, long facies in those OSAS subjects who had large tonsils
NA	None	Cephalometry	Kikuchi et al ²⁶¹	IV	29 suspected OSAS 41 controls	OSAS: long facies
Questionnaire	None	Cephalometry	Kulnis et al ²⁶²	IV	28 snorers 28 controls	Snorers: retrognathia, shorter maxilla and cranial base
Standardized history	Nap PSG	Cephalometry	Zucconi et al ²⁶³	III	26 snorers 26 controls	Snorers: retrognathia, decreased nasopharyngeal space
NA	PSG	MRI	Schiffman et al ⁸⁹	III	24 OSAS 24 controls	No difference in mandibular size between OSAS and controls
Clinical assessment of tonsillar size	Ambulatory cardiorespiratory recordings	Acoustic pharyngometry Cephalometry	Monahan et al ⁹⁰	I	203	Degree of OSAS correlated with airway size on pharyngometry but not with tonsillar size. Pharyngometric measures also correlated with mandibular length on cephalometry, only 78% of 8- to 11-y-old children could produce minimally acceptable data, and only 54% could produce high-quality data
Questionnaire, clinical examination	PSG	Rhinometry	Rizzi et al ⁹¹	IV	73	Nasal resistance of 0.59 Pa/cm ³ /s had a positive predictive value of 97% and a negative predictive value of 86%

levels. The authors concluded that oximetry alone was not adequate for the diagnosis of OSAS. On the basis of these limited studies, it seems as if oximetry alone is insufficient for the diagnosis of OSAS because of the high rate of inconclusive test results and the poor sensitivity and specificity compared with PSG, probably, in part, because children may have OSAS that results in arousals and sleep fragmentation but little desaturation. In addition, children tend to move a lot during sleep, which can result in movement artifact.

Ambulatory PSG

The term “ambulatory PSG” is used for unattended sleep studies conducted

in the home. Frequently, ambulatory PSG consists of cardiorespiratory recordings alone. Although the use of ambulatory PSG is considered appropriate under certain circumstances in adults,⁹⁹ there is a paucity of studies evaluating ambulatory PSG in children. Zucconi et al¹⁰⁰ evaluated a home portable system comprising measurements of airflow (by using thermistery), snoring, chest and abdominal wall movements, electrocardiography (ECG), position, and oximetry (level II). However, the portable system was used in the sleep laboratory for the purpose of the study. A small sample of 12 children, 3 to 6 years of age, underwent routine PSG and in-laboratory portable testing

on a consecutive night with the portable system. The portable system had good sensitivity for detecting a respiratory distress index (RDI) >5/hour (78% with automated scoring; 89% with human scoring) but a specificity of zero. Rosen et al¹⁹ reported on a study of 664 children aged 8 to 11 years who underwent abbreviated ambulatory study (by using induc-tance plethysmography, oximetry, heart rate, and position) (level III). Of these home studies, 94% were considered technically adequate. A subsample of 55 children also underwent full laboratory PSG. Few details were given regarding this subsample. However, it was reported that the ambulatory studies had a sensitivity

TABLE 14 Utility of Cardiovascular Parameters in Predicting OSAS

Measure	Sleep Evaluation	Source	Level	No.	Findings
Pulse rate	Oximetry	Constantin et al ⁶³	IV	25 OSAS	Pulse rate decreases in children who have OSAS after AT
Pulse rate	Home cardiorespiratory studies	Noehren et al ²⁶⁴	III	5 OSAS 20 controls	Pulse rate changes poor at detecting differences between respiratory events and movements, and between central and obstructive apneas
Heart rate variability	PSG	Deng et al ⁶⁴	IV	34 OSAS 18 controls	Heart rate chaos intensity had sensitivity of 72% and specificity of 81% for OSAS
Pulse transit time	PSG	Katz et al ²⁶⁵	III	24 SDB 10 controls	Depending on the severity of the event, 80%–91% of obstructive respiratory events were associated with pulse transit time changes. However, pulse transit time changes also occurred with spontaneous arousals from sleep
Heart rate, pulse transit time	PSG	Foo et al ²⁶⁶ (similar data published in Foo and Lim ²⁶⁷)	III	15 suspected OSAS	Pulse rate had 70% sensitivity and 89% specificity, and pulse transit time had 75% sensitivity and 92% specificity in identifying obstructive events
Peripheral arterial tonometry	PSG	Tauman et al ²⁶⁸	II	40 OSAS 20 controls	Peripheral arterial tonometry had sensitivity of 95% and specificity of 35% in identifying EEG arousals

of 88% and specificity of 98% in diagnosing a laboratory PSG-based AHI >5/hour. It is not clear why the results of this study were so different from that of Zucconi et al but may possibly be related to the older age of the subjects. Goodwin et al¹⁰¹ used a full PSG system, including EEG measurements, in the unattended home environment in 157 children aged 5 to 12 years (level IV). Adequate data were obtained from 91% of subjects on the first attempt and 97% when the test was repeated if needed. Data were reported as excellent in 61% of cases and good in 36%. In a small subsample of 5 subjects, data were similar to those with laboratory PSG. This study shows the feasibility of performing unattended full ambulatory PSG in older children, but results may not be the same for young children. In summary, ambulatory PSG seems to be technically feasible in school-aged children, although data are not available for younger children. Studies of differing levels, and studying different age groups, found widely discrepant specificities for diagnosing moderate OSAS. Clearly, additional studies are needed.

Nocturnal PSG

Nocturnal, attended, laboratory PSG is considered the gold standard for

diagnosis of OSAS because it provides an objective, quantitative evaluation of disturbances in respiratory and sleep patterns. A recent review describes some of the relationships between PSG and sequelae of OSAS (see “Pediatric Issues” section in Redline et al¹⁰²). PSG allows patients to be stratified in terms of severity, which helps determine which children are at risk for sequelae (thus alerting pediatricians to screen for complications of OSAS); which children are at risk for postoperative complications and would, therefore, benefit from inpatient observation postoperatively; and which children are at high risk of persistence of OSAS postoperatively, who may then need postoperative PSG to assess the need for further treatment (eg, CPAP).

Adult patients may sleep poorly the first time they are in a sleep laboratory because of anxiety, the unfamiliar environment, and the attached sensors. This “first night effect” can lead to altered sleep architecture and possible underestimation of the severity of OSAS. Five studies (levels I–IV) evaluated the night-to-night variability of PSG in children^{101,103–106}; in one of these articles,¹⁰¹ only a small subsample had night-to-night variability evaluated (Table 15). The time difference between PSGs varied from 24

hours to 4 weeks. Although some of the studies showed minor differences in respiratory parameters from night to night, the studies suggest that few children would have been clinically misclassified on the basis of a single night's PSG. Thus, 1 night of PSG seems to be adequate to establish the diagnosis of OSAS. All studies showed significant differences in sleep architecture from night to night. Therefore, research studies evaluating sleep architecture would require >1 night of PSG. For consistency, it is recommended that PSG be performed and scored by using the pediatric criteria from the American Academy of Sleep Medicine scoring manual.¹⁰⁷

Other Tests

The shape of the maximal flow-volume loop on pulmonary function testing has been used to attempt to screen for OSAS in adults. Young children cannot perform standard maximal flow-volume loops. One small study of 10 subjects evaluated the relationship between tidal breathing flow-volume loops and PSG (level III).¹⁰⁸ The sensitivity was 37.5% and specificity was 100%, indicating that this method is of limited utility in screening for OSAS.

Two studies by the same group evaluated whether urinary/serum

TABLE 15 Night-to-Night Variability in Polysomnographic Respiratory Parameters

Time Between Evaluations	Source	Level	No.	Findings
1–4 wk	Katz et al ¹⁰³	I	30 suspected OSAS	No significant group difference in the AHI between nights. Those with the highest AHI had the most variability. However, no patient was reclassified as primary snoring versus OSAS on the basis of the second study
7–50 d	Goodwin et al ¹⁰¹	IV	12	Used unattended home PSG. Studies were successful in 10. No difference in AHI between nights in this small sample
Consecutive nights	Scholle et al ¹⁰⁵	III	131 OSAS	No difference in AHI between nights
Consecutive nights	Li et al ¹⁰⁴	III	46 obese 44 controls	AHI was greater on night 2 The first night would have correctly identified 11 (85%) of the 13 cases of OSAS if the worst obstructive apnea index over any single night was used as the criterion. However, the 2 cases that would have been missed by the single PSG had only borderline OSAS
Consecutive nights	Verhulst et al ¹⁰⁶	I	70 suspected OSAS	First night classified OSAS correctly in 91% of subjects, if the worst AHI over any night was used as the diagnostic criterion. All but 1 of those who were missed had an AHI <5/h

proteomic analysis could be used to screen for the presence of OSAS. In a level I study of urinary proteomics, the investigators found that a combination of urinary proteins could predict OSAS with a sensitivity of 95% and a specificity of 100%.¹⁰⁹ Similarly, in a level III study from the same group, the investigators found that a different set of proteins could be used to identify 15 of 20 children who had OSAS and 18 of 20 children who were snorers.¹¹⁰ The authors note that they studied a highly selected population matched for age, gender, ethnicity, BMI, and inflammatory respiratory disorders, such as allergic rhinitis or asthma. Thus, this technique, although promising, requires further validation in typical clinical cohorts and duplication in another laboratory.

Summary

In summary, few of the screening techniques mentioned here have a sensitivity and specificity high enough to be relied on for clinical diagnosis. In addition, it should be noted that many of the studies used an AHI >5/hour when determining

sensitivity and specificity, although an AHI >1.5/hour is considered statistically abnormal in children.^{111–113} Few studies used large study samples, and few were blinded. As a result, some of the studies of screening techniques resulted in contradictory evidence. On a pragmatic level, however, it is realized that current infrastructure is inadequate to provide PSG for all children with suspected OSAS. Therefore, the use of screening tests may be better than no objective testing at all. However, clinicians using these tests should familiarize themselves with the sensitivity and specificity of the test used and consider proceeding to full PSG if the test result is inconclusive.

Areas for Future Research

- Well-designed, large, controlled, blinded, multicenter, prospective studies are required to provide more definitive answers regarding the utility of screening tests for the diagnosis of OSAS. In particular, additional studies of ambulatory PSG in children of varying ages are needed.

TREATMENT OF OSAS

AT

Adenotonsillar hypertrophy is the most common cause of OSAS, and AT continues to be the primary treatment for this issue. Adenoidectomy alone may not be sufficient for children who have OSAS because it does not address oropharyngeal obstruction secondary to tonsillar hyperplasia. The previous guideline stated the importance of AT as the primary treatment for OSAS in children. No new literature is available to suggest a change to these recommendations. Table 3 in the guideline lists relative contraindications to AT. Note that whereas a submucous cleft palate is a relative contraindication to adenoidectomy, a partial adenoidectomy may be performed in such patients. However, postoperative PSG should be performed to ensure that OSAS has resolved.

AT in most children is associated with a low complication rate. Minor complications include pain and poor oral intake. More severe complications may include bleeding, infection, anesthetic complications, respiratory decompensation, velopharyngeal incompetence, subglottic stenosis, and, rarely, death.

Tarasiuk et al found that health care utilization costs were 226% higher in children with OSAS before diagnosis compared with control children¹¹⁴ and that health care costs decreased by one-third in children who underwent AT, whereas there was no change in health care costs in control children or children who had untreated OSAS¹¹⁵ (both studies were level IV).

Partial Tonsillectomy

Several newer techniques for tonsillectomy have gained increasing use since publication of the last guideline. The primary goal of these techniques

is to decrease the morbidity associated with traditional tonsillectomy methods. One such technique is partial tonsillectomy (PT), in which a portion of tonsil tissue is left to cover the musculature of the tonsillar fossa. Multiple studies, ranging in level from II to IV, have evaluated recovery times and adverse effects from PT. However, only a few small, lower-level studies have specifically looked at the effect of PT on OSAS. In a level IV study, Tunkel et al¹¹⁶ evaluated 14 children who underwent PSG before and after PT and found a cure rate (AHI ≤ 1 /hour) of 93% postoperatively. In a retrospective study (level IV), Mangiardi et al¹¹⁷ compared 15 children who underwent PT (of 45 eligible) with 15 children who underwent total tonsillectomy. This study had a number of technical limitations. A variety of techniques (overnight laboratory PSG, nap sleep studies, and limited-channel home sleep studies) were performed in subjects preoperatively, and limited-channel home sleep studies were performed in all patients postoperatively. These different monitoring techniques would be expected to provide varying results.^{118,119} In both surgical groups, the authors found a higher rate of postoperative OSAS than typically reported in the literature, with a median (range) AHI of 7.5 ± 4.3 /hour in the PT group and 8.8 ± 4.7 /hour in the total tonsillectomy group (not significant).

PT carries an increased risk of regrowth of the tonsils, which occurred in 0.5% to 16% of patients in studies of varied duration. Celenk et al¹²⁰ performed a retrospective review of 42 children 1 to 10 years of age who underwent PT via radio-frequency ablation for symptoms of OSAS (level IV). Follow-up ranged from 6 to 32 months, with a mean follow-up of 14 months. They found tonsillar regrowth on physical examination in 7

(16.6%) patients; 5 of these were symptomatic and underwent completion tonsillectomy. The time frame for occurrence of regrowth ranged from 1 to 18 months. The authors noted that some episodes of regrowth occurred after episodes of tonsillitis. Zagólski¹²¹ evaluated 374 children who underwent PT on the basis of clinical symptoms of OSAS (level IV). Patients underwent otolaryngology examinations annually for 4 years. Twenty-seven (7.2%) children had tonsillar regrowth; of those, 20 had clinical symptoms and, therefore, underwent completion tonsillectomy. Regrowth of the palatine tonsils was observed at a mean period of 3.8 years, suggesting the need for long-term follow-up. In a multicenter, retrospective case series of 870 children with a mean follow-up of 1.2 years, Solares et al¹²² found an incidence of tonsillar regrowth of 0.5% (level III). The methods and criteria for assessing regrowth were not detailed in this article but may have been a clinical follow-up at 1 and 6 months postoperatively. The lower rate of regrowth in this study compared with the other studies may have been related to the shorter follow-up period. Eviatar et al¹²³ performed a long-term (10–14 years), retrospective, telephone survey comparing 33 children who had undergone PT for symptoms of OSAS versus 16 children who underwent tonsillectomy; children undergoing concomitant adenoidectomy were excluded (level III). They found similar rates of parent-reported snoring in the 2 groups (6.1% for PT, 12.5% for total tonsillectomy; not significant) but no cases of OSAS on the basis of symptoms.

PT for the treatment of adenotonsillar hypertrophy has shown some success in decreasing immediate postoperative pain. Derkay et al¹²⁴ prospectively evaluated 300 children undergoing

either PT or total tonsillectomy for adenotonsillar hypertrophy (level II). They found that children in the PT group had an earlier return to normal activity and were 3 times more likely not to need pain medication at 3 days compared with the total tonsillectomy group. There was no difference between groups in median return to a normal diet (3.0 vs 3.5 days). In a level III, retrospective study of 243 children undergoing PT versus 107 undergoing total tonsillectomy, Koltai et al¹²⁵ found less pain and quicker return to a normal diet in children undergoing PT. In a level II study, Sobol et al¹²⁶ prospectively evaluated 74 children who had adenotonsillar hypertrophy scheduled for AT. Their results showed a resumption to normal diet 1.7 days earlier in the PT group compared with children undergoing total tonsillectomy. There was no significant difference in the resolution of pain or return to normal activities between the 2 groups, but there was increased intraoperative blood loss in the PT group.

In summary, there are no level I studies comparing PT with total tonsillectomy in the pediatric population. Additional data are needed regarding the efficacy of PT for OSAS, by using objective outcome measurements. There is possibility of tonsillar regrowth after PT, with studies showing varied rates of regrowth. These studies are all limited by lack of blinding, lack of objective measures to quantitate tonsillar regrowth, and lack of polysomnographic data relating tonsillar regrowth to OSAS. Some studies found that patients who undergo PT have less pain and quicker recovery during the first few days compared with children undergoing total tonsillectomy. However, PT may be associated with greater intraoperative blood loss, and there is a risk of recurrent infections in the tonsillar remnants.^{120,121,123} At

this point, data are insufficient to recommend any particular surgical technique for tonsillectomy over another in terms of OSAS. However, children undergoing PT should be monitored carefully long-term to ensure that symptoms of OSAS related to tonsillar regrowth do not occur, and families should be warned about the possibility of recurrence of OSAS.

Postoperative Management After AT

Tonsillectomy and adenoidectomy can be safely performed in the vast majority of children on an outpatient basis. Risk factors that increase the risk of postoperative complications include age <3 years, severe OSAS, presence of cardiac complications, failure to thrive, obesity, and presence of upper respiratory tract infection (URI). Although there have been numerous publications regarding postoperative complications since publication of the last guideline, there have been no data to suggest a change in the previous recommendations. Children with medical comorbidities such as craniofacial anomalies, genetic syndromes, and neuromuscular disease are also high risk; these special populations are not covered by this guideline.

An important advantage of the objective documentation of the severity of OSAS by using PSG should be the ability to predict the need for overnight hospital stay after AT on the basis of a higher risk of postoperative complications. Severe OSAS has been proposed as a criterion for inpatient observation; the current evidence to define severe OSAS is derived primarily from level III retrospective studies. Although considerable physiologic information regarding the respiratory pattern and gas exchange during sleep is available from an overnight PSG, the available studies

have focused primarily on the AHI and, to a lesser degree, the nadir of the SpO_2 . Relevant studies are listed in Table 16. Studies varied with regard to the type of patients included (proportion of obese patients; patients who had craniofacial and genetic syndromes) and severity of OSAS. Although the definition of postoperative respiratory compromise varied, most studies required that an intervention (eg, supplemental oxygen, nasopharyngeal tube, CPAP, intubation) be performed. Most studies found a high rate of postoperative respiratory complications. Different studies showed different PSG predictive factors for postoperative complications, and few studies developed receiver operating characteristic curves.¹²⁷ Nevertheless, studies were fairly consistent in indicating that an SpO_2 <80% and an AHI >24/hour were predictive of postoperative respiratory compromise. These criteria are more conservative than the recently published clinical practice guidelines from the American Academy of Otolaryngology–Head and Neck Surgery, which recommend that children who have an AHI $\geq$ 10/hour and/or an SpO_2 nadir <80% be admitted for overnight observation after AT.³

It is difficult to provide exact PSG criteria for OSAS severity because these criteria will vary depending on the age of the child; additional comorbidities, such as obesity, asthma, or cardiac complications of OSAS; and other PSG criteria that have not been evaluated in the literature, such as the level of hypercapnia and the frequency of desaturation (compared with SpO_2 nadir). Therefore, on the basis of published studies (Table 16), it is recommended that patients who have an SpO_2 nadir <80% (either on preoperative PSG or during observation in the recovery room postoperatively) or an AHI $\geq$ 24/hour be

observed as inpatients postoperatively because they are at increased risk of postoperative respiratory compromise. In addition, on the basis of expert consensus, it is recommended that patients with significant hypercapnia on PSG (peak $P_{CO_2} \geq$ 60 mm Hg) be admitted postoperatively. Clinicians may decide to admit patients who have less severe PSG abnormalities on the basis of a constellation of risk factors (age, comorbidities, and additional PSG factors) on an individual basis.

Data regarding URIs were based on studies of children undergoing general anesthesia for a variety of procedures. The committee could not identify any studies related specifically to URIs and AT. In a large, level III study, Tait et al¹²⁸ evaluated 1078 children 1 month to 18 years of age who were undergoing an elective surgical procedure. The presence of a URI was diagnosed by using a parental questionnaire. Data regarding perioperative respiratory events were recorded. There were no differences between children who had active URIs, recent URIs (within 4 weeks), and asymptomatic children with respect to the incidences of laryngospasm and bronchospasm. However, children who had active and recent URIs had significantly more episodes of breath-holding, desaturation <90%, and overall adverse respiratory events than children who had no URIs. Independent risk factors for the development of adverse respiratory events in children who had active URIs included use of an endotracheal tube (in those <5 years of age), preterm birth, history of reactive airway disease, paternal smoking, surgery involving the airway, the presence of copious secretions, and nasal congestion. In a large level III study of 831 children undergoing surgery with a laryngeal mask airway, von Ungern-Sternberg et al¹²⁹

TABLE 16 Relationship Between PSG Parameters and Postoperative Respiratory Complications

Source	Level	Type of Study	No.	Study Group	Age, y	Special Populations Included ^a	Findings
Hill et al ²⁶⁹	III	Retrospective	83	AHI >10	≤18	Yes	Major respiratory complication in 5%; minor in 20% Only age <2 y ($P < .01$) and AHI >24 ($P < .05$) significantly predicted postoperative airway complications Complication rate only 4% if special populations were excluded AHI >24 predicted 63% of complications
Jaryszak et al ²⁷⁰	III	Retrospective	151	Any child who had a PSG	Not stated	Yes	Respiratory complication rate was 15% Children with complications had higher AHI (32 vs 14) and lower SpO ₂ nadir (72% vs 84%) compared with those without complications
Koomson et al ²⁷¹	III	Retrospective	85	AHI >5	Not stated	Yes	Postoperative desaturation in 28% More likely to desaturate postoperatively if PSG SpO ₂ nadir <80%
Ma et al ²⁷²	III	Retrospective	86	Any child who had a PSG	1–16	Yes	Postoperative desaturation in 7% No difference in AHI between those with and without postoperative desaturation (11.6 ± 4.5 vs 14.7 ± 16.6)
Sanders et al ²⁷³	I	Prospective	61	61 children who had OSAS vs 21 who had tonsillitis	2–16	No	Respiratory complication rate was 28% Subjects with RDI ≥30 were more likely to have laryngospasm and desaturation At an RDI ≥20, OSAS was more likely to have breath-holding on induction
Schroeder et al ²⁷⁴	III	Retrospective	53	Severe OSAS (AHI >25)	Not stated	Yes	43% required oxygen or PAP Note: an additional 17 children were electively kept intubated postoperatively
Shine et al ¹⁹⁶	III	Retrospective	26	Obese OSAS	2–17	Obese; other comorbidities not stated	46% had respiratory complications Those requiring intervention for respiratory problems had a lower SpO ₂ ($68 \pm 20\%$ vs $87 \pm 18\%$) but no difference in RDI (27 ± 44 vs 15 ± 28) than those who did not require intervention By using univariate analysis, a preoperative SpO ₂ <70% was associated with postoperative respiratory compromise, but no threshold was found for RDI
Ye et al ¹²⁷	III	Retrospective	327	AHI ≥5	4–14	No	11% had respiratory complications An AHI of 26 had 74% sensitivity and 92% specificity for predicting postoperative respiratory complications

^a Special populations include children with genetic syndromes and craniofacial abnormalities.

compared children who had a URI within 2 weeks of surgery versus those without a URI; 27% of children had a recent URI. They found a doubling of the incidence of laryngospasm, bronchospasm, and oxygen desaturation intraoperatively and in the recovery room in the children who had recent URIs, although the overall incidence of these events was low. The risk was highest in young children; those undergoing ear, nose, and throat surgery; and those in whom multiple attempts were made to insert the laryngeal mask airway. On the basis of data available regarding risk with general anesthesia,

the committee concluded that children who have an acute respiratory infection on the day of surgery, as documented by fever, cough, and/or wheezing, are at increased risk for postoperative complications and, therefore, should be rescheduled or monitored closely postoperatively. Clinicians should decide on an individual basis whether these patients should be rescheduled, taking into consideration the severity of OSAS in the particular patient and keeping in mind that many children who have adenotonsillar hypertrophy exhibit chronic rhinorrhea and nasal congestion even in the absence of viral infections.

Postoperative Persistence of OSAS After AT

Although the majority of children have a marked improvement in OSAS after AT, OSAS may persist postoperatively. OSAS is especially likely to persist in children who have underlying illnesses such as craniofacial anomalies, Down syndrome, and neuromuscular disease; these special populations are not included in this review.

Over the years since the committee's first consensus report, a number of studies have been published discussing the impact of surgery on childhood OSAS. Most of these studies were omitted from consideration for

this review because of their lack of preoperative and postoperative PSGs. Many other studies reported changes in group averages for polysomnographic and other measures postoperatively. All published articles found that AT leads to significant improvement in polysomnographic parameters in the majority of patients (although not in all). Studies providing data that could be interpreted to provide an estimate of the proportion of patients who were cured of their OSAS are shown in Table 17. Twenty original articles on the topic have been published since 2002, including 2 meta-analyses^{130,131} of other articles included in the review. The lack of uniform agreement regarding the polysomnographic criteria for diagnosis of OSAS complicates this analysis of postoperative persistence of OSAS, as it does other aspects of this review, in part because the preoperative PSG criteria for surgery are not uniform across the different articles, but more importantly, because the postoperative prevalence of OSAS is highly dependent on the stringency of diagnostic criteria. In some cases, articles helpfully provided data on residual prevalence of OSAS by using different polysomnographic criteria (eg, $AHI > 1/\text{hour}$ and $AHI > 5/\text{hour}$). At this point, it is generally accepted that AT has a higher success rate than isolated adenoidectomy or tonsillectomy, so although a few of the articles included some patients undergoing only adenoidectomy, only tonsillectomy, or ancillary procedures such as nasal turbinectomy, most focused exclusively on the impact of AT.

As shown in Table 17, a total of 11 articles were published, describing 10 general population cohorts referred either to a pediatric sleep specialist or otolaryngologist for OSAS, and 1 meta-analysis of articles dating back to 1980. Most of these were case

series of patients, with significant methodologic flaws, including nonblinding and incomplete follow-up for a high proportion of patients, and these issues were present even in the methodologically strongest articles.^{132–134} The polysomnographic criteria for OSAS in each article may or may not have been the same as those used as an indication for AT, and these varied from an $AHI \geq 1/\text{hour}$ to $AHI \geq 5/\text{hour}$ and $RDI > 2$ to $5/\text{hour}$. Surprisingly, the overall estimate of postoperative persistence of OSAS did not seem to vary greatly by polysomnographic criteria for surgery. Conversely, the estimates of residual OSAS were clearly related to which polysomnographic criteria for OSAS were applied to the postoperative PSGs. When using an $AHI \geq 1/\text{hour}$ as the criterion for residual OSAS, estimates of persistence ranged from 19%¹³⁵ to 73%,¹³³ whereas when using an $AHI \geq 5/\text{hour}$ as the criterion, the estimate of persistence of OSAS ranged from 13%¹³⁴ to 29%.¹³² It is important to recognize that there are clearly recognizable risk factors for postoperative persistence of OSAS and that the prevalence of these risk factors in the populations studied had an important impact on their estimates of postoperative persistence of OSAS. For example, >50% of patients in the multicenter study of Bhattacharjee et al¹³³ were obese, whereas 21% of the patients in the series by Ye et al¹³⁴ were obese, defined as 95th percentile for the Chinese population. It should be emphasized that although many of these studies showed a high proportion of patients with residual OSAS after AT, most patients exhibited a marked decrease in AHI postoperatively.

Risk Factors for Postoperative OSAS

1. Obesity

Five studies focused attention on obese patients (defined as 95th percentile for weight or BMI for age), and 1

meta-analysis¹³¹ combined 4 of these studies. The meta-analysis reported that 88% of obese patients still had a postoperative $AHI \geq 1/\text{hour}$, 75% had a postoperative $AHI \geq 2/\text{hour}$, and 51% had a postoperative $AHI \geq 5/\text{hour}$. Preoperative obesity was found to be a significant risk factor for postoperative residual OSAS in several other studies^{133–135} as well, even when multivariable modeling was used to control for other factors such as age and preoperative AHI . The odds ratios of persistent OSAS in obese patients ranged in these models from 3.2¹³⁴ to 4.7.¹³⁶ One study found that the relationship of BMI to risk of persistent OSAS was no longer significant when adjusted for preoperative AHI .¹³⁷ In contrast to all of the studies that looked at this factor, a study of obese Greek children found no difference in the prevalence of residual OSAS in obese versus nonobese children; part of the reason for this finding might be that this study used a slightly less stringent criterion for obesity (1.645 SDs weight for age, which is the 90th percentile).¹³⁸

2. Baseline Severity of OSAS

All studies that evaluated baseline AHI as a potential risk factor for persistent postoperative OSAS found it to be a significant risk factor, even when adjusted for other comorbidities such as obesity.^{132–134,136,139}

3. Age

A series limited to children aged <3 years reported a high incidence (65%) of treatment failures in these younger children, but this cohort included a large proportion of children who have other risk factors, such as severe OSAS and chromosomal and craniofacial abnormalities.¹⁴⁰ In contrast, 2 studies reported that increasing age (especially 7 years and older) is a risk factor for persistent

TABLE 17 Studies Providing an Estimate of the Proportion of Patients Who Were Cured of OSAS With Surgery

Source	Year	Level	No.	Age, y	Population	Polysomnographic Criterion for Surgery	Operation	Follow-up Period, mo	Subjects Who Had OSAS at Follow-up	Miscellaneous
General population studies										
Chervin et al ¹³⁷	2006	I	39	5.0–12.9		AHI ≥ 1	AT	13 $\pm$ 1.4	21%	2 articles documented findings in the same population
Dillon et al ²⁷⁵										
Guilleminault et al ¹³⁵	2004	III	56	1.25–12.5		AHI ≥ 1 or RDI > 2	AT: 36 (some of whom also had nasal turbinectomy and/or tonsillar wound suturing); A: 8; T: 11	3	AT: 19.4%; A: 100%; T: 100%	Half of AT failures were in obese patients
Guilleminault et al ¹⁴¹	2007	III	199	1.5–14		AHI ≥ 1	AT in 183; A or T in 19; nasal turbinectomy in 17.4%	3–5	46.2%	Increased nasal turbinate score, presence of deviated nasal septum and increased Mallampati score of relationship of tongue to uvula and retro position of the mandible were all predictive of higher failure rate
Guilleminault et al ²⁷⁶	2004	IV	284	2–12.1		AHI > 1.5	AT in 228; A or T inferior turbinectomy in 73	3–4	8.8% of those with preoperative AHI < 10 and AT; 64.7% of those with preoperative AHI ≥ 10 . No breakdown provided regarding results of AT versus other surgery	An additional 99 children had RDI > 1.5 and AHI < 1.5 . Of this group, 100% had normal RDI after AT and 9.2% had residual abnormal RDI after A or T. Difficult to interpret findings because of inconsistent reporting of data
Mitchell ¹³²	2007	III	79	3–14		AHI ≥ 5	AT	1–9.3	16% (AHI ≥ 5); 29% (AHI > 1.5)	Severity of preoperative AHI predicted response: preoperative 5–10, 0% ≥ 5 ; preoperative 10–20, postoperative 12% ≥ 5 ; preoperative > 20 , postoperative 36% ≥ 5 ; 13/22 with postoperative snoring had AHI ≥ 5 ; 0/57 without postoperative snoring had AHI ≥ 5
Tal et al ²⁷⁷	2003	IV	36	1.8–12.6		RDI > 1	AT	4.6 (1–16)	11.11% had RDI > 5	
Tauman et al ¹³⁷	2006	III	110	6.4 $\pm$ 3.9		AHI ≥ 1	AT	1–15	46% AHI 1–5, 29% with AHI > 5	In logistic regression, AHI before surgery and family history of OSAS were significant predictors of AHI > 5 postoperative
Walker et al ²⁷⁸	2008	IV	34	0.93–5		RDI > 5 in REM sleep	AT	9.8	35% with RDI > 5	Treatment failures limited to those with preoperative RDI in REM > 30
Bhattacharjee et al ¹³³	2010	III	578	6.9 $\pm$ 3.8		AHI ≥ 1	AT	1–24	72.8% with AHI ≥ 1 ; 21.6% > 5	Large multicenter study. Age > 7 y, increased BMI, presence of asthma, and high preoperative AHI were independent predictors of persistent postoperative OSAS

TABLE 17 Continued

Source	Year	Level	No.	Age, y	Population	Polysomnographic Criterion for Surgery	Operation	Follow-up Period, mo	Subjects Who Had OSAS at Follow-up	Miscellaneous
Brietzke and Gallagher ¹³⁰	2006	III	325	4.9	Various	AHI ≥ 1	AT	3.3	17.1% (depended on OSAS criteria for each study)	Meta-analysis of 11 case series published between 1980 and 2004
Ye et al ¹³⁴	2010	IV	84	7.1 $\pm$ 3.2	Chinese	AHI ≥ 5	AT	18–23	31% with AHI ≥ 1 ; 13.1% with AHI ≥ 5	Obesity and high preoperative AHI were significant independent predictors of treatment failure
Focus on obese populations										
Mitchell and Kelly ²⁷⁹	2004	III	30	3.0–17.2	Obese (BMI > 95th percentile)	AHI >5	AT	5.6	54%	
Mitchell and Kelly ¹³⁹	2007	III	72	3–18	Comparison of obese (BMI >95th percentile) with nonobese	AHI ≥ 2 : AHI 2–5 mild, AHI 5–15 moderate AHI ≥ 15 severe	AT	5–6	Obese: 76%: (46% mild; 15% moderate; 15% severe). Nonobese: 28%: (18% mild; 10% moderate).	Preoperative AHI and obesity were independent risk factors for postoperative OSAS. OR for persistent OSAS in obese, adjusted for preoperative AHI, was 3.7 (95% CI: 1.3–10.8)
O'Brien et al ¹³⁶	2006	III	69	7.1 $\pm$ 4.2	Obese (weight >2 SDs from mean for age)	RDI ≥ 5	AT	20.4 $\pm$ 16.8	Nonobese: 22.5%; Obese: 55%	Preoperative AHI and obesity were independent risk factors for postoperative OSAS. OR for persistent OSAS in obese, adjusted for preoperative AHI, was 4.7 (95% CI: 1.7–11.2)
Shine et al ¹⁹⁴	2006	IV	19	6.5 $\pm$ 4.4	Obese (BMI >95th percentile)	RDI >5	18 AT (1 with UPPP), 1 T	2–6	63%	Missing data
Costa and Mitchell ¹³¹	2009	III	110	7.3–9.3	Obese	Various	AT	3–5.7	88% had postoperative AHI ≥ 1 ; 75% had postoperative AHI ≥ 2 ; 51% had postoperative AHI ≥ 5	Meta-analysis of 4 obesity studies included here
Apostolidou et al ¹³⁸	2008	IV	70	6.5 $\pm$ 2.2	Greek; obese defined as >1.645 SDs from mean weight for age	OAHl ≥ 1	AT	2–14	Overall: 75.7% with AHI ≥ 1 (77.3% obese, 75% nonobese). Among children with a preoperative OAHl ≥ 5 : 9% with AHI ≥ 5 (8% obese, 10% nonobese)	
Focus on other special populations										
Mitchell and Kelly ¹⁴⁰	2005	III	20	1.1–3.0	Children <3 y	RDI >5	AT	4.1–20.4	65%: 25% RDI 5–10; 25% RDI 10–20; 15% RDI >20	Included comorbidities (Down syndrome, cardiac disease, cerebral palsy) excluded from this guideline. 60% of patients were severe, with RDI >20 at baseline
Mitchell and Kelly ²⁸⁰	2004	III	29	1.4–17	Severe OSAS	RDI >5; severe: RDI ≥ 30	AT	6	69% with postoperative RDI >5	48% were obese

A, adenoidectomy; CI, confidence interval; OAHl, obstructive AHI; OR, odds ratio; T, tonsillectomy; REM, rapid eye movement; UPPP, uvulopharyngopalatoplasty.

OSAS, even when controlling for obesity.^{132,133}

4. Other Potential Risk Factors

Individual studies have noted that nasal abnormalities or craniofacial disproportion,¹⁴¹ family history of OSAS,¹³⁷ and presence of asthma¹³³ were all predictive of higher failure rate, but these findings were not substantiated by other studies. Of note, Mitchell¹³² found that 13 of 22 patients in the cohort who had postoperative snoring had an AHI ≥ 5 /hour, whereas none of the 57 patients who did not exhibit postoperative snoring had an AHI ≥ 5 /hour. This supports the findings of older studies reviewed in the previous technical report that found absence of snoring to have a 100% negative predictive value for postoperative OSAS.⁶ However, in the Chinese cohort, 2 of 11 patients who have persistent AHI ≥ 5 /hour reportedly did not snore; it is unclear whether cultural considerations might have affected parental report of snoring.¹³⁴

Summary

AT is the most effective surgical therapy for pediatric patients, leading to an improvement in polysomnographic parameters in the vast majority of patients. Despite this improvement, a significant proportion of patients are left with persistent OSAS after AT. The estimate of this proportion in a relatively low-risk population ranges from a low of 13% to 29% when using an AHI ≥ 5 /hour as the criterion to a high of 73% when including obese children and adolescents and a conservative AHI ≥ 1 /hour. Children at highest risk of persistent OSAS are those who are obese and those with a high preoperative AHI, especially those with an AHI ≥ 20 /hour, as well as children >7 years of age. Absence of snoring postoperatively is

reassuring but may not be 100% specific; it may therefore be advisable to obtain a postoperative PSG in very-high-risk children even in the absence of reported persistent snoring.

Areas for Future Research

- What are the risks of persistence of OSAS and long-term recurrence of OSAS after PT versus total tonsillectomy? Large, prospective, randomized trials with objective outcome measures including PSG are needed.
- Better delineation of which patients would benefit from postoperative PSG.
- How well does resolution of OSAS correlate with resolution of complications of OSAS?
- Are some of the newer surgical techniques for AT equally effective in resolving OSAS?
- What are the risks of performing AT in a patient with a URI?
- What are the PSG parameters that predict postoperative respiratory compromise? Future research should focus on refining the AHI and SpO₂ nadir cutoffs for severe OSAS. In addition, it may be possible to glean other predictive information from the PSG, such as the extent of hypoventilation, the percent sleep time spent with SpO₂ $<90\%$, the frequency of desaturation events, the length of apneas and hypopneas, and the presence of central apneas, to create formulae for risk scores.

CPAP

At the time of the previous report, there were few prospective studies on CPAP use in children, although several retrospective studies indicated that CPAP was efficacious in the treatment of pediatric OSAS. Since that time, there have been at least 7 recent

studies evaluating the use of positive airway pressure (PAP) in children and adolescents who have OSAS. One of these was a randomized trial with low power (level II),¹⁴² and others were case series without controls (level IV). A descriptive study examined the use of behavioral intervention in improving CPAP adherence.¹⁴³ In addition, a level III study described use of a high-flow nasal cannula as an alternative to CPAP.¹⁴⁴ In contrast to the previous guidelines, several of the current studies obtained objective evaluation of CPAP adherence by downloading usage data from the CPAP device. In most studies, CPAP therapy was instituted for persistent OSAS after AT; in many cases, the patients had additional risk factors for OSAS, such as obesity or craniofacial anomalies.

A multicenter study (level II) evaluated PAP in 29 children who were randomly assigned either CPAP or bilevel positive airway pressure (BPAP).¹⁴² Patients demonstrated significant improvement in sleepiness, snoring, AHI, and oxyhemoglobin saturation while using PAP during the 6-month follow-up period. However, approximately one-third of patients dropped out, and of those who used PAP, objective adherence was 5.3 ± 2.5 hours/night. Parents overestimated the hours of PAP use compared with the devices' actual objective recordings of use. There was no significant difference in adherence between the CPAP and BPAP groups. A retrospective chart review of 46 children started on PAP for OSAS that persisted after AT also showed significant improvement in symptoms of OSAS as well as in polysomnographic parameters (level IV).¹⁴⁵ Seventy percent of patients were considered adherent. Parental report of adherence was most divergent from the machines' recording in the least adherent patients. More

than one-half of the children had complicating factors, such as Down syndrome and Prader-Willi syndrome.¹⁴⁵ Another study of a heterogeneous group of patients displayed varying CPAP adherence, with 31 of 79 children showing continued CPAP use (level IV).¹⁴⁶ A small, nonblinded retrospective study (level IV) suggested that adherence to CPAP could be improved with behavioral techniques if the family accepted the interventions.¹⁴³

A retrospective review described 9 children who successfully used BPAP in the intensive care setting because of respiratory compromise after AT.¹⁴⁷ Another retrospective review described the successful use of CPAP in 9 patients of a heterogeneous group of 18 children aged <2 years.¹⁴⁸ A nonrandomized, prospective level III study of 12 children who had OSAS treated in the sleep laboratory with a high-flow open nasal cannula system as an alternative to formal CPAP demonstrated an improvement in oxyhemoglobin saturation and arousals, but not AHI, compared with baseline.¹⁴⁴ There was a decrease in sleep efficiency with the cannula compared with baseline. Long-term use and use in the home situation were not assessed.

In summary, several studies (levels II–IV) have confirmed earlier data demonstrating that nasal CPAP is effective in the treatment of both symptoms and polysomnographic evidence of OSAS, even in young children. However, adherence can be a major barrier to effective CPAP use. For this reason, CPAP is not recommended as first-line therapy for OSAS when AT is an option. However, it is useful in children who do not respond adequately to surgery or in whom surgery is contraindicated. Patient and family preference may also be a consideration (eg, in families with

religious beliefs against surgery or blood transfusions). Objective assessment of CPAP adherence is important because parental estimates of use are often inaccurate. If the patient is nonadherent, then attempts should be made to improve adherence (eg, by addressing adverse effects, by using behavior modification techniques), or the patient should be treated with alternative methods. A study described in the previous report noted that CPAP pressures change over time in children, presumably because of growth and development.¹⁴⁹ Therefore, it is recommended that CPAP pressures be periodically reassessed in children.

At this time, data are insufficient to make a recommendation on the use of high-flow, open nasal cannula systems.

Areas for Future Research

- Efficacy of CPAP use as a first-line treatment of obese children.
- Determinants of CPAP adherence and ways to improve adherence.
- Long-term effects of CPAP, particularly on the development of the face, jaw, and teeth.
- Changes in CPAP pressure over time, and the frequency with which this needs to be monitored.
- Development of pediatric-specific devices and interfaces.

Medications

There have been several studies evaluating the use of corticosteroids and leukotriene antagonists in the treatment of OSAS. An older study showed no therapeutic effect of systemic steroids on OSAS.¹⁵⁰ Since then, 3 studies (1 level I, 1 level II, and 1 level III) have evaluated topical nasal steroids as treatment of OSAS, 1 level II study has evaluated montelukast, and 1 level IV study has evaluated a combination thereof. An additional

level I study evaluated the effect of intranasal steroids on adenoidal size and symptoms related to adenoidal hypertrophy but did not include PSG in the evaluation.¹⁵¹

A small, level II, randomized, double-blind trial,¹⁵² a level I, randomized, double-blind trial of 62 children,¹⁵³ and a nonrandomized, open-label level III study of intranasal steroids¹⁵⁴ all showed a moderate improvement in patients who had mild OSAS. However, significant residual OSAS remained in 2 of the studies. Berlucchi et al¹⁵¹ reported an improvement in symptoms of adenoidal hypertrophy, including snoring and observed apnea, but did not obtain objective evidence of improvement in OSAS. Two studies showed shrinkage of adenoidal tissue.^{151,153} All studies were short term (2–6 weeks), although 1 study showed persistent improvement 8 weeks after discontinuation of the steroids (Table 18).¹⁵³

An open-label, nonrandomized, 16-week level IV study of montelukast in children who had mild OSAS found a statistically significant but small change in the AHI (AHI decreased from 3.0 ± 0.2 to 2.0 ± 0.3 ; $P = .017$).⁸² Another small, open-label, nonrandomized, 12-week level IV study of combined montelukast and nasal steroids found a mild but statistically significant improvement in AHI in children who had mild OSAS (AHI decreased from 3.9 ± 1.2 /hour to 0.3 ± 0.3 /hour; $P < .001$).¹⁵⁵

In summary, several small level I through IV studies suggest that topical steroids may ameliorate mild OSAS. However, the clinical effects are small. On the basis of these studies, intranasal steroids may be considered for treatment of mild OSAS (defined, for this indication, as an AHI <5/hour, on the basis of studies described in Table 18). Steroids should not be used as the primary treatment of moderate

TABLE 18 Studies of Antiinflammatory Medications for the Treatment of OSAS

Medication	Source	Level	No.	Duration, wk	Randomized	Placebo-Controlled	Baseline AHI (per h)	AHI on Treatment (per h)	P
Intranasal steroids	Brouillette et al ¹⁵²	II	13 OSAS 12 controls	6	Yes	Yes	10.7 ± 9.4	5.8 ± 7.9	.04
Intranasal steroids	Alexopoulos et al ¹⁵⁴	III	27 OSAS	4	No	No	5.2 ± 2.2	3.2 ± 1.5	<.001
Intranasal steroids	Kheirandish-Gozal and Gozal ¹⁵³	I	62 OSAS	6; crossover	Yes	Yes	3.7 ± 0.3	1.3 ± 0.2	<.001
Montelukast	Goldbart et al ⁸²	IV	24 OSAS 16 controls	16	No	No	3.0 ± 0.2	2.0 ± 0.3	.017
Intranasal steroids + montelukast	Kheirandish et al ¹⁵⁵	IV	22 OSAS 14 controls	12	No	No	3.9 ± 1.2	0.3 ± 0.3	<.001

or severe OSAS. Because the long-term effects of intranasal steroids are not known, follow-up evaluation is needed to ensure that the OSAS does not recur and to monitor for adverse effects. Of note, no studies specifically evaluated children who had atopy or chronic rhinitis, although 1 study mentioned that similar improvements were seen in children who had a history of allergic symptoms compared with those without.¹⁵³ Further study to determine whether children who have atopy are more likely to respond to this therapy is needed. Data are insufficient at this time to recommend treatment of OSAS with montelukast.

Areas for Future Research

- What is the optimal duration of intranasal steroid use? All trials have been short-term with a short-term follow-up. Does the OSAS recur on discontinuation of therapy? How often should objective assessment of treatment effects be performed?
- What is the efficacy of intranasal steroids in children who have chronic or atopic rhinitis?
- How do the benefits and adverse effects of long-term nasal steroids compare with surgery?
- Larger studies, stratified for severity of OSAS and controlled for obesity, to determine whether OSAS is associated with systemic inflammation

- Will these biomarkers be good outcome measurements for treatment studies? Do they correlate with clinical outcomes or long-term prognosis?

Rapid Maxillary Expansion

Rapid maxillary expansion has recently been used to treat OSAS in select pediatric populations. It is an orthodontic procedure designed to increase the transverse diameter of the hard palate by reopening the midpalatal suture. It does this by means of a fixed appliance with an expansion screw anchored on selected teeth. After 3 to 4 months of expansion, a normal mineralized suture is built up again. The procedure is typically used only in children with maxillary constriction and dental malocclusion. Two case series without controls (level IV) have evaluated this procedure as a treatment of OSAS in children. One study described 31 patients selected from an orthodontic clinic; 4 months after surgery, all patients had normalized AHI.¹⁵⁶ Another screened 260 patients in a sleep center to find 35 that were eligible; only 14 were studied.¹⁵⁷ There was a significant improvement in signs and symptoms of OSAS as well as polysomnographic parameters. In summary, rapid maxillary expansion is an orthodontic technique that holds promise as an alternative treatment of OSAS in children. However, data are insufficient to recommend its use at this time.

Areas for Future Research

- A randomized controlled trial to assess the efficacy of rapid maxillary expansion in the treatment of OSAS in children.

Positional Therapy

Several level IV, retrospective studies evaluated the effect of body position during sleep on OSAS. The studies had conflicting results. One study found that young children had an increased AHI in the supine position,¹⁵⁸ and another study found that young children did not have a positional change in AHI but older children did.¹⁵⁹ Another study found an increased obstructive apnea index but not AHI (except in the obese subgroup) in the supine position,¹⁶⁰ whereas a study of obese and nonobese children, which controlled for sleep stage in each position, found that AHI was lowest when children were prone.¹⁶¹ No study evaluated the effect of changing body positions or the feasibility of maintaining a child in a certain position overnight. Therefore, at this point, no recommendations can be made with regard to positional therapy for OSAS in children.

Other Treatment Options

Specific craniofacial procedures, such as mandibular distraction osteogenesis, are appropriate for select children with craniofacial anomalies. However, a discussion of these children is beyond the scope of this

guideline. Minimal experience is available regarding intraoral appliances in children.¹⁶² A tracheotomy is extremely effective at treating OSAS but is associated with much morbidity and is typically a last resort if CPAP and other treatments fail to offer improvement for a child who has severe OSAS.

OBESITY AND OSAS

This section reviews the evidence regarding the relationships between obesity and SDB (this term is used to encompass both snoring and OSAS, especially in studies that did not distinguish between these entities) in the pediatric population. The prevalence of childhood obesity is increasing,¹⁶³ and many studies on obesity and OSAS have been published since the last guideline. Because childhood obesity has a major impact on OSAS, it is described in detail in this report. Obesity is defined as BMI >95th percentile for age and gender.

Epidemiology: Obesity as a Risk Factor for Snoring and OSAS

A number of large, cross-sectional, community-based studies including more than 21 500 children have examined the risk of SDB conferred by overweight and obesity (Table 19). The majority of these studies obtained information regarding potential SDB from questionnaires, but some included objective measurements such as oximetry or overnight PSG. Similarly, many studies based the determination of BMI on data from questionnaires. The ages ranged from 6 to 17 years, consistent with recruitment strategies using local schools. Countries from around the world are represented, including North America, Asia, Europe, and the Middle East. Taken together, these studies indicate that the risk of snoring in children is increased

twofold to fourfold with obesity (defined as BMI $\geq$ 90th or 95th percentile). When analyzed, BMI was found to be an independent risk factor for snoring.

Several studies based on surveys of thousands of children, in some cases supplemented by use of physical examinations, showed that overweight/obesity was associated with an increased prevalence of snoring (Table 19).^{47,164–167} Fewer studies that included objective measurements to identify SDB were available. Two population-based studies using PSG demonstrated a relationship between overweight/obesity and OSAS.^{11,12} In contrast to the findings of the majority of studies, Brunetti et al²³ found that although HS was more prevalent in obese children in a sample of schoolchildren, there was no difference in the incidence of OSAS on PSG among the subset of normal-weight, overweight, and obese children who have HS who had abnormal overnight oximetry results. Similar to the population-based studies, studies using case series or subjects recruited from sleep disorders programs (some of which use PSG and some of which use surveys) also showed a relationship between weight and SDB.^{168,169}

From these studies, it can be concluded that obesity is an independent risk factor for snoring and OSAS. The range of evidence from individual studies was II to III (Table 19) and on the aggregate rise to level I. The studies reported on large numbers of children recruited from community-based samples, some of whom had face-to-face examinations and measurements. Data obtained in different settings yielded similar results. The impact of race, if any, is not yet clear. Population-based studies of Hispanic children, a group at high risk of obesity and related comorbidities, are not

yet available.¹⁶³ For the clinician, it is recommended that particular attention is needed for screening obese and overweight children for signs and symptoms of OSAS, with a low threshold for ordering diagnostic tests. Future research should focus on population-based studies, with objective measurements of both measures of adiposity and PSG, and should include larger numbers of African American and Hispanic youth.

Predictors of Obesity-Related SDB

A number of program-based studies provide information regarding the predictors for SDB in obese children. Carotenuto et al⁸⁸ reported via data gathered from parental questionnaires that in obese subjects referred for obesity evaluation and nonobese controls randomly selected from schools, the waist circumference z score correlated with symptoms of SDB ($R = 0.37$, $P < .006$) but BMI and subcutaneous fat did not (level III). Verhulst et al¹⁷⁰ examined 91 consecutive overweight or obese children referred for PSG and found that OSAS was not related to indices of obesity, including bioelectric impedance analysis fat mass (level III). Central apnea was significantly predicted by using BMI score, waist circumference, waist-to-hip circumference ratio, and percent fat mass. Tonsillar size was the only significant correlate in their model for moderate to severe OSAS. In a retrospective review of 482 Chinese children referred for PSG and evaluated by using BMI and a tonsillar grading scale, the group of 111 obese children had a significantly higher median AHI and percentage with AHI >1.5/hour than did the nonobese group (level III).¹⁷¹ In a regression analysis of log AHI as dependent variable, BMI and tonsil grade were predictors, but age and gender were not. In a large study of schoolchildren in

TABLE 19 Risk of SDB Conferred by Overweight and Obesity

Source	Level	Type of Study	No.	Duration	Diagnostic Technique	Other Features	Findings	P for Obesity as a Risk Factor
Urschitz et al ¹⁶⁴	II	Community-based sample of third graders	1144	1 y	Parental report of snoring, BMI, SES, risk factors for rhinitis, asthma	Habitual snorers reassessed at 1 y, with 49% continuing to snore	BMI $\geq 90\%$ conferred a 4 times higher risk of HS versus a BMI $< 75\%$; 25% of obese subjects had HS	
Corbo et al ¹⁶⁶	II	Community-based sample of 10- to 15-y-old children from 10 schools	2439	2 y	Parental questionnaire and nasal examination and BMI by physician		Snoring increased significantly with BMI $> 90\%$ and was > 2 times for BMI $> 95\%$ vs $< 75\%$	.000
Shin et al ⁴⁷	IV	Cross-sectional community-based sample of high school students	3871	NA	Questionnaire (tested for reliability) completed by subject, caretakers, and sleep partner	Korean children; 81% response rate to survey	Snoring frequency was significantly associated with increasing BMI	$< .001$
Bidad et al ¹⁶⁷	II	Cross-sectional study of 11- to 17-y-old children	3300	NA	Scripted face-to-face interview and measurements of BMI and tonsil size by physician	7.9% of sample with HS (≥ 3 nights per week when well)	> 2 -fold risk of snoring in overweight or obesity	
Stepanski et al ¹⁶⁸	III	Case series; mean age: 5.9 ± 3.7 y	190	NA	Clinical interview, PSG	68% with SDB (≥ 5 AHI, $< 90\%$ SpO_2 , sleep fragmentation, ECG changes)	BMI was higher in the SDB group	$< .01$
Rudnick et al ¹⁶⁹	III	Compared children scheduled for AT with control group from same urban setting	170 SDB 129 controls	NA	BMI, ethnicity		African American children who had SDB were more likely to be obese than African American children who did not have SDB	$< .02$
Li et al ¹²	II	Cross-sectional study of 13 primary schools	6447 by questionnaire 410 high risk and 209 low risk with exam and PSG	NA	Questionnaire in all with PSG and examination in high-risk group and low-risk subset for comparison	Hong Kong 9172 sampled with 70% response rate	Male gender, BMI, and AT size were independently associated with OSA	
Li et al ¹⁷²	II	Cross-sectional study of 13 primary schools; same population as previous study	6349	NA	Questionnaire	Designed to determine prevalence of HS and associated symptoms.	Prevalence of HS was 7.2%; male gender, BMI, parental HS, nasal allergies, asthma were associated with snoring	$< .0001$
Brunetti et al ²³	II	Cross-sectional; mean age 7.3 y	1207 screened, 809 eligible	NA	Questionnaire in all followed by oximetry in the 44 who had HS; PSG in subset who had abnormal oximetry results	Southern Italy	HS more common in the obese group; no difference in OSA by PSG across weight groups	.02
Bixler et al ¹¹	II	Cross-sectional study of grades K–5	5740 had questionnaire 700 randomly selected for PSG, 490 completed	NA	Questionnaire followed by PSG in subset	Prevalence of AHI > 5 1.2%. Strong linear relationship between waist circumference and BMI with SDB	Waist circumference associated with all levels of SDB, also nasal complaints and minority race	
Urschitz et al ¹⁶⁵	III	Cross-sectional community-based of primary schoolchildren	995	NA	Overnight oximetry		Overweight, smoke exposure, respiratory allergies were independent risk factors for sleep hypoxemia	

AT, adenotonsillar; K, kindergarten; NA, not available; OSA, obstructive sleep apnea.

Hong Kong, Li et al reported that male gender, BMI score, and tonsillar size were independently associated with OSAS (level II).^{12,172} In 490 US school-children studied by using overnight PSG, Bixler et al¹¹ found waist circumference to be an independent risk factor for all levels of severity of OSAS (level II). Urschitz et al¹⁶⁵ studied 995 children in a cross-sectional, program-based study in Germany and divided those with SDB into mild (SpO_2 nadir 91%–93%), moderate (<90%), and recurrent hypoxemia (>3.9 episodes of desaturation per hour of sleep) groups (level III). Overweight (BMI >75th percentile) was found to be an independent risk factor for mild, moderate, and recurrent hypoxemia during sleep.

From these studies, it is observed that the distribution of body fat may be more important in predicting SDB than BMI alone. In addition, tonsillar size is important in predicting SDB, even in obese children. The authors of these articles comment that SDB is likely more complicated in obese children, with obesity contributing to gas exchange and respiratory pattern abnormalities. Obesity can result in decreased lung volumes, abnormal central nervous system ventilatory responses, decreased upper airway caliber, a potential impact of leptin on ventilation, and other factors. Taken together, the strength of the evidence for these study findings is level II. Findings are limited by the fact that controls were drawn from different populations than subjects and that the studies did not all reach the same conclusions regarding the importance of body fat distribution. The latter may have been affected by the use of different measurement techniques. Anthropomorphic measurement thresholds that indicate increased risk for SDB in children would be of use to clinicians. It is recommended that

clinicians consider fat distribution (eg, waist circumference) and not just BMI in their assessment of the risk of SDB.

Comorbidities: Interactions Between Obesity and SDB

Cardiovascular

Adults who have SDB and are obese are at increased risk of cardiovascular disease, including systemic hypertension and blunting of the normal decrease in BP during sleep (nocturnal dipping). This section deals with the evidence that children and adolescents who are obese and have SDB may be similarly at risk. Six studies evaluating SDB, obesity, and cardiovascular complications in children are available. Reade et al¹⁷³ retrospectively evaluated 130 patients referred for PSG and described 56 obese subjects (BMI >95th percentile), of whom 70% had hypertension and 54% had OSAS (level IV). Among the 34 non-obese subjects, only 8% ($P < .0005$) had hypertension and 29% had OSAS ($P < .05$). The authors concluded that BMI was a significant determinant of both SDB and diastolic BP, with the number of hypopneas predictive of diastolic BP in both weight categories. In a community-based sample of 760 Greek children evaluated by using morning BP measurements, BMI, and a questionnaire regarding sleep habits, Kadiotis et al¹⁷⁴ identified 50 children who had HS (level IV). They found that 28% of the children in the HS group were obese versus 15% of nonsnoring children (significance not reported). They reported that HS had no impact on BP, but that age, gender, and BMI were significant covariates in predicting systolic BP; inclusion of HS in this analysis did not affect these relationships. Similar findings were identified for diastolic BP, with the exception that age had no effect. This study compared absolute BP

measurements rather than the variance from normal values on the basis of race, age, gender, and body size. Because children from 4 to 14 years of age were included, this may have affected the results and conclusions. Kohyama et al¹⁷⁵ examined 32 Asian subjects referred for PSG and measured overnight BP every 15 minutes. In this study, obstructive apneas and hypopneas were identified indirectly and, thus, could have been underestimated or overestimated compared with studies with more direct measurements of airflow (level IV). Subjects were divided into low (<10 obstructive events per hour; 16 subjects) and high AHI (>10 obstructive events per hour; 7 subjects). Of the total, 23 subjects tolerated the BP measurements. Three subjects were obese. BMI predicted the systolic BP during rapid eye movement sleep ($P < .001$) but did not predict any of the diastolic BP indices. Li et al¹⁷⁶ performed a population-based study of 306 Asian children 6 to 13 years of age who had overnight PSG and ambulatory day and night BP measurements (level III). Children who had primary snoring were excluded, and those who had OSAS were divided into normal, mild, and moderate (AHI >5) groups. Multiple linear regression analysis revealed significant associations for the severity of hypoxemia and AHI with day and night BP, respectively, independent of obesity. Although BP levels both awake and asleep increased with the severity of OSAS, obesity and waist circumference partially accounted for elevations in sleep systolic BP and sleep mean arterial pressure but not for diastolic BP measurements. Amin et al¹⁷⁷ studied 88 children who had OSAS ranging in severity from mild to severe and 52 controls matched for age and gender. They used PSG, ambulatory BP measurements, and actigraphy (level III). The obese SDB group, compared with the nonobese SDB group, had higher

waking systolic BP ($P < .001$) and sleeping systolic BP ($P = .02$) after adjusting for severity of SDB. They concluded that there was no difference between the effects of SDB and obesity on waking systolic or diastolic BP or sleeping systolic BP but did find that SDB had a greater contribution to sleeping diastolic BP than did obesity. In summary, this group of articles demonstrates that both obesity and SDB are associated with increased day and night BP in children, although hypertension per se is rare (aggregate evidence level III). It seems that after controlling for obesity, significant independent effects of SDB remain and that hypoxemia and the frequency of obstructive events, perhaps via sleep disruption or intrathoracic fluid shifts, are important. Practitioners should be aware that children and adolescents who have OSAS are at increased risk of elevated BP. Future studies would benefit from a treatment arm to determine whether BP improves with resolution of sleep apnea, as well as longitudinal studies to determine the impact of pediatric obesity related-SDB on adult hypertension.

Metabolic

Obesity is a risk factor for impaired glucose tolerance, liver disease, abnormal lipid profiles, and other metabolic derangements. OSAS has been explored as a possible contributor to these metabolic abnormalities. Ten articles were reviewed. Verhulst et al¹⁷⁸ studied 104 overweight/obese children and adolescents with Tanner staging, overnight PSG, oral glucose tolerance testing, lipid profile, and BP measurements (level IV). The subjects were divided into normal, mild, and moderate/severe SDB groups. Findings consistent with the metabolic syndrome were present in 37%. Those who had a moderate degree of SDB had a higher BMI z score than the

normal group, and the waist-to-hip circumference ratio increased across the 3 SDB groups. The severity of SDB was independently correlated with impaired glucose homeostasis and worse lipid profile. Mean SpO_2 and SpO_2 nadir during sleep were significant predictors of the metabolic syndrome ($P = .04$ for both). A community-based cohort of 270 adolescents was studied by Redline et al¹⁷⁹ using PSG, oral glucose tolerance testing, homeostatic model assessment (HOMA [a measure of insulin sensitivity]), BMI, waist circumference, BP measurements, Tanner stage, sleep diary, SES, and birth history (level II). Metabolic syndrome was defined as having at least 3 of the following 5 features: (1) waist circumference $>75\%$ of normal; (2) mean BP or diastolic BP $>90\%$ of normal or receiving current therapy for hypertension; (3) elevated triglycerides; (4) low high-density lipoprotein; or (5) abnormal oral glucose tolerance or fasting glucose test results. Twenty-five percent of the sample was overweight, and 19% were deemed to have metabolic syndrome. The authors found that children who had metabolic syndrome had more severe hypoxemia and decreased sleep efficiency and that as AHI severity increased, there was a progressive increase in the number of children who had metabolic syndrome ($P < .001$). Both overweight children and those who had metabolic syndrome were more prevalent in the SDB group ($P < .001$) and more were male. Age, race, birth history, and SES did not vary with SDB. With adjustment for BMI, the SDB group had higher BP, fasting insulin, and more abnormal HOMA and lipid profile. They concluded that adolescents who experience SDB are at a sevenfold increased risk of metabolic syndrome and that the relationship is not explained by gender, race, or SES and,

furthermore, persists with adjustment for BMI percentile.

A study by Kaditis et al¹⁸⁰ of 110 children (2–13 years of age) referred for snoring did not find an impact of SDB on glucose homeostasis in nonobese children. The subjects were divided into $AHI \geq 5/h$ and $<5/h$; the authors found no difference in HOMA, insulin, glucose, or lipid concentrations between the 2 groups (level III). There was no relationship identified between PSG indices and HOMA or fasting insulin. BMI, age, and gender were significant predictors for fasting insulin and HOMA in multiple linear regression analysis. They speculated that OSAS may have more detrimental effects in obese than in nonobese young subjects. Similarly, Tauman et al¹⁸¹ studied 116 subjects referred for PSG, one-half of whom were obese, and 19 nonsnoring controls. The authors found no impact of SDB indices on metabolic parameters (level III). Only BMI and age were important, and there was no relationship between SDB and surrogate measures of insulin resistance. They concluded that obesity was the major determinant of insulin resistance and dyslipidemia. In obese children, data from de la Eva et al¹⁸² demonstrated that the severity of OSAS correlated with fasting insulin levels, independent of BMI (level III). Of note, the study by Redline et al¹⁷⁹ included children older than those in the studies by Kaditis et al¹⁸⁰ and Tauman et al¹⁸¹; thus, the variation in the findings may be a function of the length of time SDB had been present or perhaps attributable to the strong influence puberty has on glucose homeostasis. Kelly et al¹⁸³ compared 37 prepubertal and 98 pubertal children in a study by using PSG, HOMA, adiponectin (an insulin-sensitizing hormone secreted by adipose tissue) measurements, as well as urinary catecholamine metabolites (level III).

Tanner stage was determined by self-attestation. In the prepubertal children, they found no association between polysomnographic parameters and metabolic measurements after correcting for BMI. Elevated fasting insulin (≥ 20 $\mu\text{U/mL}$) was significantly more common in the OSAS group ($P = .03$), even when corrected for BMI. When pubertal obese subjects were considered separately, the risk of elevated fasting insulin ($P = .04$) and impaired HOMA was greater in the OSAS group ($P = .05$). Pubertal children who had OSAS also had lower adiponectin and higher urinary catecholamine levels, even when controlled for BMI. Kelly et al concluded that OSAS further predisposes obese children to metabolic syndrome, likely through multiple mechanisms involving adipose tissue and the sympathetic nervous system.

In a study that included pretreatment and posttreatment measurements in 62 prepubertal children who had moderate to severe OSAS, Gozal et al¹⁸⁴ found that although nonobese children had no change in measures of glucose homeostasis after treatment of OSAS, obese children had a significant improvement even while BMI remained stable ($P < .001$) (level II). Similar effects were not seen in non-obese children. Treatment (AT) improved the lipid profile and inflammatory markers in both obese and nonobese children.

Other studies have examined different aspects of altered metabolism in obesity-related OSAS. Kheirandish-Gozal et al¹⁸⁵ found elevated alanine transaminase (a marker for fatty liver) in a large sample of obese children who had OSAS (level IV). Verhulst et al¹⁸⁶ found elevated serum uric acid (a marker of oxidative stress) in 62 overweight children who had OSAS, with a significant relationship between the severity of OSAS and

serum uric acid independent of abdominal adiposity ($P = .01$) (level IV). Verhulst et al¹⁸⁷ demonstrated that, in a group of 95 obese and overweight children, total white blood cell and neutrophil counts increased with hypoxemia, and they speculated that inflammation may contribute to cardiovascular morbidity in obesity-related SDB (level IV).

In summary, as expected, this group of studies confirms that obesity increases the risk of insulin resistance, dyslipidemia, and other metabolic abnormalities in children. The role that OSAS plays in altering glucose metabolism is still not entirely clear but is likely less important in younger children and in lean children. Conflicting studies exist regarding the independent effect of OSAS on metabolic measures when it coexists with obesity in children. Puberty has an important role in this relationship. Screening of obese children who have OSAS for markers of metabolic syndrome should be considered, especially in the adolescent age group. Individual studies were level II through IV, with an aggregate level of III.

Neurobehavioral

The neurobehavioral complications of OSAS are discussed in detail elsewhere in this technical report. However, 6 studies have explored the potential contribution of obesity to behavior and cognition in children with OSAS and will be discussed in this section. A subanalysis of the Tucson Children's Assessment of Sleep Apnea Study evaluating parent-rated behavioral problems in overweight children before and after controlling for OSAS was performed by Mulvaney et al (level II).¹⁸⁸ They analyzed data from 402 subjects, 15% of whom were overweight; data were derived from home overnight PSG, the Conners scale, and the Child Behavior Checklist

(CBCL). They found that, after controlling for OSAS, behaviors such as withdrawal and social problems were higher in obese children compared with nonobese children. This finding emphasizes the need to control for obesity when designing studies evaluating neurobehavioral issues in children with OSAS. Chervin et al⁴² evaluated students in the second and fifth grades in 6 elementary schools (level IV). Only 146 of 806 surveys were returned. Parental survey of health, race, BMI, Pediatric Sleep Questionnaire, teacher-rated performance, and SES were collected. SDB was associated with African American race, SES, and poor teacher ratings ($P < .01$), but only SES was independently associated with school performance. Low SES was not associated with SDB when controlled for BMI. The authors concluded that future studies evaluating the relationship between school performance and SDB should incorporate direct measurements of SES and obesity. Owens et al¹⁸⁹ examined all children evaluated at a tertiary center for sleep problems between 1999 and 2005; they used PSG, BMI, the Children's Sleep Health Questionnaire, and a mental health history, including the CBCL (level IV). In this study of 235 participants, 56% had a BMI >85 th percentile and were thus considered overweight. They found modest correlations between measures of SDB and both somatic complaints and social problems but not with other behavioral complaints. Increased BMI was associated with total CBCL score, internalizing, social, thought, withdrawn, anxious, somatic, and aggressive behavior domains in a dose-response fashion ($P = .03$), thus emphasizing the need to control for obesity in future studies. Short sleep also correlated with a number of subscales on the CBCL ($P < .001$). Additional sleep disorders added to the risk of behavior

problems ($P < .001$). BMI predicted both total and internalizing CBCL scores, and sleep duration predicted externalizing scores. The presence of an additional sleep diagnosis was the strongest predictor of all 3 CBCL scores. They concluded that overweight, insufficient sleep, and other sleep disorders should be considered when evaluating and treating behavioral problems associated with SDB. Beebe et al²¹ studied 60 obese subjects recruited from a weight-management program compared with 22 controls; tools used included BMI; parent- and self-reported validated sleep, behavior, and mood questionnaires; actigraphy; and PSG (level IV). They reported that the obese group had later bedtimes ($P < .05$), shorter ($P < .01$) and more disrupted sleep ($P < .05$), more symptoms of OSAS ($P < .001$), sleepiness ($P = .009$), parasomnias ($P = .007$), higher AHI ($P < .01$), and poorer school performance. Another study by Beebe et al¹⁹⁰ of 263 overweight subjects enrolled in a hospital-based weight-management program found a negative relationship between the severity of OSAS and school performance and parent- and teacher-reported behaviors that persisted with adjustment for gender, race, SES, sleep duration, and BMI (level IV). Interestingly, Roemmich et al¹⁹¹ found a relationship between a decrease in motor activity and increasing weight in overweight children after surgical treatment of OSAS by using AT ($P = .03$) (level IV). They hypothesized that a decrease in physical activity and “fidgeting” energy expenditure were responsible for the weight gain. However, because obese controls without surgery were not studied, it is unclear whether the degree of weight gain was greater than typically seen in obese children.

In summary, these studies point to obesity as a potential important factor

in childhood performance, mood, and behavior (aggregate level III). Clinicians should be aware that children who are obese and have OSAS might continue to have difficulties in these domains after treatment of OSAS. It is recommended that sleep habits and nonrespiratory sleep complaints be included in the evaluation and treatment of obesity-related OSAS. The relationship between SES, obesity, and OSAS is complex and adds further emphasis to the premise that studies of behavior and cognition must be carefully designed and controlled.

QoL

Both obesity and OSAS can affect health-related QoL. Two studies have examined measures of QoL in children who are obese and have OSAS. In a study of 151 overweight children by Carno et al¹⁹² that used surveys of QoL and SDB and PSG, overweight youth who have OSAS were found to have lower self- and parent-related QoL (level IV). Neither objective measures of OSAS by PSG nor BMI correlated with QoL, whereas reported symptoms of OSAS did ($P < .05$). Similarly, Crabtree et al¹⁹³ compared 85 children 8 to 12 years of age who had been referred for OSAS and who underwent PSG, BMI, QoL ascertainment, and the Children's Depression Inventory with a control group with previously documented normal PSG (level IV). They found that OSAS did not differ between obese and nonobese children and that there was no difference in QoL between children who snore and have OSAS. The referred SDB group had lower QoL scores than the control group ($P < .001$), but the authors found no difference between obese and nonobese SDB subjects or in those with OSAS versus snoring. They concluded that children who snore have a lower QoL than non-snoring controls, and that this finding

was not related to obesity of the severity of SDB.

In summary, QoL is an important outcome measure that may be more related to perceived symptoms of OSAS than measured physiologic disturbances of sleep and breathing, even in the obese patient (aggregate level IV). The impact of obesity on QoL in children with SDB is yet to be determined by using population-based studies and is an important outcome measure to be included in longitudinal and treatment studies.

Surgical Treatment of OSAS in the Obese Child

Surgical treatment of OSAS in general is discussed in detail in the technical report, but 5 studies have examined this area in obesity-related OSAS and are discussed here. Shine et al¹⁹⁴ evaluated 19 obese patients treated with AT (level IV). Although OSAS improved significantly ($P < .01$), only 37% of patients were deemed cured (defined as a postoperative AHI < 5 /hour), and 10 (53%) subjects needed CPAP postoperatively. A level IV retrospective review by Spector et al¹⁹⁵ included 14 patients who were morbidly obese who were electively sent to the ICU after AT (per policy). One patient needed intubation, and 2 patients required BPAP. Another retrospective review of 26 morbidly obese patients, all of whom were sent to the ICU after AT as per routine, found that 14 patients (54%) had an uncomplicated postoperative course, and 12 (45%) required respiratory intervention, including 1 requiring intubation and 2 requiring BPAP.¹⁹⁶ Costa and Mitchell¹³¹ evaluated the response to AT in a meta-analysis of 4 studies that included 110 obese children who had OSAS (level III). They found that OSAS improved but did not resolve after AT, with 88% of children having an AHI > 1 /hour and 51% of

children having an AHI >5/hour postoperatively. Apostolidou et al¹³⁸ reported on 70 snoring children with a mean age of 5.8 ± 1.8 years who underwent AT; 22 (31%) were obese (level IV). PSG was performed both preoperatively and postoperatively. They found no difference in cure rates between obese and nonobese subjects who had OSAS, by using an AHI <1/hour as the definition of cure. However, there was an improvement in AHI in both groups, and approximately 90% of all subjects had an AHI <5/hour postoperatively.

In summary, few studies have evaluated the effects of AT in the obese child who has OSAS, and studies have been of a low level of evidence (aggregate level IV). Studies suggest that the AHI may improve significantly after AT, even in obese children, supporting the idea that surgery may be a reasonable first-line treatment, even in obese patients. However, better-level studies are needed to assess the effects of AT in obese children and adolescents, including evaluation of subgroups such as adolescents and the morbidly obese. A significant number of children required intubation or CPAP postoperatively, which reinforces the need for inpatient observation in obese children postoperatively. Studies have not been performed to determine whether children at high risk who are obese and have OSAS, such as those with pulmonary or systemic hypertension, waking hypoventilation, or pathologic daytime sleepiness, may benefit from stabilization with BPAP therapy before undergoing AT to decrease the risk of postoperative complications.

Weight Loss and Other Nonsurgical Treatments

There is a paucity of data regarding the effects of weight loss on OSAS in children and adolescents. Verhulst

et al¹⁹⁷ found that weight loss was a successful treatment of OSAS in a group of 61 adolescents being cared for in a residential weight loss treatment program (level IV). Davis et al⁴⁹ studied the effects of exercise in 100 overweight children by administering the Pediatric Sleep Questionnaire before and after enrollment in a no-exercise group, a low-dose aerobic exercise program, or a high-dose aerobic exercise program for 3 months (level IV). They found no change in BMI, but 50% of children who screened positive for SDB improved to a negative screening result after intervention. They found their results to be consistent with a dose-response effect of exercise on improvement in SDB ($P < .001$). Academic achievement did not improve in concert with changes in the Pediatric Sleep Questionnaire. Kalra et al¹⁹⁸ showed a significant improvement in OSAS after bariatric surgery, in association with a mean weight loss of 58 kg (level IV). In summary, along with many other health-related benefits, achieving weight loss and increasing exercise seem to be beneficial for OSAS and should be recommended along with other interventions for OSAS in obese children and adolescents (aggregate level IV). However, it should be noted that the 2 weight loss studies involved treatment regimens that are not commonly available to the majority of obese children. The effects of more modest weight loss regimens require further evaluation.

Pulmonary Disease and Obesity-Related SDB

Two studies addressed the relationship between obesity-related SDB and pulmonary disease. This has been described in adults as the “overlap syndrome,” when chronic obstructive pulmonary disease and OSAS are present in the same individual. As part

of the Cleveland Children's Sleep and Health Study, Sulit et al¹⁹⁹ evaluated parent-reported wheeze and asthma, history of snoring, and PSG in 788 participants (level III). They found that children who experienced wheeze and asthma were more likely to be obese ($P = .0097$) and concluded that SDB may partially explain this finding. They speculated that obesity changes airway mechanics and that SDB may increase gastroesophageal reflux, leptin levels, and cytokines and, thus, increase lower airways inflammation. Dubern et al²⁰⁰ studied 54 children who had BMI z scores >3, 74% of whom were pubertal, by using history, physical examination, assessment of body fat mass, Tanner stage, HOMA, lipid profile, leptin, pulmonary function tests, and PSG (level IV). They confirmed the presence of OSAS, lower functional residual capacity, increased airways resistance, lower airways obstruction, and insulin resistance in this group of morbidly obese children. Snoring and AHI correlated with BMI ($P = .01$) and neck/height ratio ($P = .03$) (adjusted for age, gender, Tanner stage, and ethnicity). Airways resistance correlated with snoring index and AHI after adjustment. These studies remind us that the upper airway is part of the respiratory system and that its function is affected by lung mechanics. Abnormalities of pulmonary mechanics related to obesity affect OSAS and may add to abnormalities of gas exchange during sleep. It is suggested that evaluation of the child who is obese and has OSAS should include a history and physical examination directed at the entire respiratory system, and pulmonary function testing may be indicated.

Areas for Future Research

- What threshold of easily obtained anthropomorphic measurements predicts a significant risk of OSAS?

Overweight as well as obese children should be included in future studies.

- Are there additive or multiplicative effects of OSAS and obesity on BP? How do these relationships evolve over time, and what is the impact of genetic and racial background? Does treatment of OSAS improve hypertension in obese children and adolescents?
- The effect of OSAS on metabolic syndrome in children and adolescents remains controversial. Future research should include treatment arms with careful measurements before and after interventions. Longitudinal studies that track changes during puberty and into adulthood would be of interest.
- Further research is needed to clarify the effects of AT on OSAS, including evaluation of subgroups such as adolescents and morbidly obese patients. There should also be studies evaluating the use of CPAP or BPAP before surgery in the obese population, as a way of stabilizing the cardiopulmonary system and reducing operative risk.

- What is the effect of modest weight loss on OSAS in children and adolescents? Research should be directed at identifying strategies to effectively implement weight loss and exercise programs in this population.

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OVERSIGHT FROM THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2009–2011

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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Sleep Apnea Clinical Practice Guideline

Quick Reference Tools

- Action Statement Summary
— Diagnosis and Management of Childhood Obstructive Sleep Apnea
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Sleep Apnea
- AAP Patient Education Handout
— *Sleep Apnea and Your Child*

Action Statement Summary

Diagnosis and Management of Childhood Obstructive Sleep Apnea

Key Action Statement 1: Screening for OSAS

As part of routine health maintenance visits, clinicians should inquire whether the child or adolescent snores. If the answer is affirmative or if a child or adolescent presents with signs or symptoms of OSAS (Table 2), clinicians should perform a more focused evaluation. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 2A: Polysomnography

If a child or adolescent snores on a regular basis and has any of the complaints or findings shown in Table 2, clinicians should either (1) obtain a polysomnogram (Evidence Quality A, Key Action strength: Recommendation) OR (2) refer the patient to a sleep specialist or otolaryngologist for a more extensive evaluation (Evidence quality D, Key Action strength: Option). (Evidence Quality: Grade A for polysomnography; Grade D for specialist referral, Recommendation Strength: Recommendation.)

Key Action Statement 2B: Alternative Testing

If polysomnography is not available, then clinicians may order alternative diagnostic tests, such as nocturnal video recording, nocturnal oximetry, daytime nap polysomnography, or ambulatory polysomnography. (Evidence Quality: Grade C, Recommendation Strength: Option.)

Key Action Statement 3: Adenotonsillectomy

If a child is determined to have OSAS, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery (see Table 3), the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSAS but does not have adenotonsillar hypertrophy, other treatment should be considered (see Key Action Statement 6). Clinical judgment is required to determine the benefits of adenotonsillectomy compared with other treatments in obese children with varying degrees of adenotonsillar hypertrophy. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 4: High-Risk Patients Undergoing Adenotonsillectomy

Clinicians should monitor high-risk patients (Table 5) undergoing adenotonsillectomy as inpatients post-operatively. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 5: Reevaluation

Clinicians should clinically reassess all patients with OSAS for persisting signs and symptoms after therapy to determine whether further treatment is required. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 5B: Reevaluation of High-Risk Patients

Clinicians should reevaluate high-risk patients for persistent OSAS after adenotonsillectomy, including those who had a significantly abnormal baseline polysomnogram, have sequelae of OSAS, are obese, or remain symptomatic after treatment, with an objective test (see Key Action Statement 2) or refer such patients to a sleep specialist. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 6: CPAP

Clinicians should refer patients for CPAP management if symptoms/signs (Table 2) or objective evidence of OSAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 7: Weight Loss

Clinicians should recommend weight loss in addition to other therapy if a child/adolescent with OSAS is overweight or obese. (Evidence Quality: Grade C, Recommendation Strength: Recommendation.)

Key Action Statement 8: Intranasal Corticosteroids

Clinicians may prescribe topical intranasal corticosteroids for children with mild OSAS in whom adenotonsillectomy is contraindicated or for children with mild postoperative OSAS. (Evidence Quality: Grade B, Recommendation Strength: Option.)

Coding Quick Reference for Sleep Apnea	
<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
327.20 Sleep apnea, organic, unspecified	G47.30 Sleep apnea, unspecified
327.21 Sleep apnea, primary central	G47.31 Primary central sleep apnea
327.23 Sleep apnea, obstructive	G47.33 Obstructive sleep apnea (adult) (pediatric) (Code additional underlying conditions.)
	J35.3 Hypertrophy of tonsils with hypertrophy of adenoids
	E66.01 Morbid (severe) obesity due to excess calories E66.09 Other obesity due to excess calories E66.3 Overweight E66.8 Other obesity E66.9 Obesity, unspecified

Sleep Apnea and Your Child



Does your child snore a lot? Does he sleep restlessly? Does he have difficulty breathing, or does he gasp or choke, while he sleeps?

If your child has these symptoms, he may have a condition known as sleep apnea.

Sleep apnea is a common problem that affects an estimated 2% of all children, including many who are undiagnosed.

If not treated, sleep apnea can lead to a variety of problems. These include heart, behavior, learning, and growth problems.

How do I know if my child has sleep apnea?

Symptoms of sleep apnea include

- Frequent snoring
- Problems breathing during the night
- Sleepiness during the day
- Difficulty paying attention
- Behavior problems

If you notice any of these symptoms, let your pediatrician know as soon as possible. Your pediatrician may recommend an overnight sleep study called a *polysomnogram*. Overnight polysomnograms are conducted at hospitals and major medical centers. During the study, medical staff will watch your child sleep. Several sensors will be attached to your child to monitor breathing, oxygenation, and brain waves. An electroencephalogram (EEG) is a test that measures brain waves.

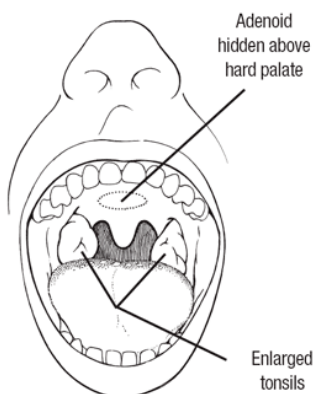
The results of the study will show whether your child suffers from sleep apnea. Other specialists, such as pediatric pulmonologists, otolaryngologists, neurologists, and pediatricians with specialty training in sleep disorders, may help your pediatrician make the diagnosis.

What causes sleep apnea?

Many children with sleep apnea have larger tonsils and adenoids.

Tonsils are the round, reddish masses on each side of your child's throat. They help fight infections in the body. You can only see the adenoid with an x-ray or special mirror. It lies in the space between the nose and throat.

Large tonsils and adenoid may block a child's airway while she sleeps. This causes her to snore and wake up often during the night. However, not every child with large tonsils and adenoid has sleep



apnea. A sleep study can tell your doctor whether your child has sleep apnea or if she is simply snoring.

Children born with other medical conditions, such as Down syndrome, cerebral palsy, or craniofacial (skull and face) abnormalities, are at higher risk for sleep apnea. Overweight children are also more likely to suffer from sleep apnea.

How is sleep apnea treated?

The most common way to treat sleep apnea is to remove your child's tonsils and adenoid. This surgery is called a tonsillectomy and adenoidectomy. It is highly effective in treating sleep apnea.

Another effective treatment is nasal continuous positive airway pressure (CPAP), which requires the child to wear a mask while he sleeps. The mask delivers steady air pressure through the child's nose, allowing him to breathe comfortably. Continuous positive airway pressure is usually used in children who do not improve after tonsillectomy and adenoidectomy, or who are not candidates for tonsillectomy and adenoidectomy.

Children who may need additional treatment include children who are overweight or suffering from another complicating condition. Overweight children will improve if they lose weight, but may need to use CPAP until the weight is lost.

Remember

A good night's sleep is important to good health. If your child suffers from the symptoms of sleep apnea, talk with your pediatrician. A proper diagnosis and treatment can mean restful nights and restful days for your child and your family.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

American Academy
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Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months

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- *Clinical Practice Guideline*

- *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



- *Technical Report*

- *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



- *2011 Commentary*

Readers of this clinical practice guideline are urged to review the technical report to enhance the evidence-based decision-making process. The full technical report is available following the clinical practice guideline and on the companion CD-ROM.

CLINICAL PRACTICE GUIDELINE

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months

SUBCOMMITTEE ON URINARY TRACT INFECTION, STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT

KEY WORDS

urinary tract infection, infants, children, vesicoureteral reflux, voiding cystourethrography

ABBREVIATIONS

SPA—suprapubic aspiration
AAP—American Academy of Pediatrics
UTI—urinary tract infection
RCT—randomized controlled trial
CFU—colony-forming unit
VUR—vesicoureteral reflux
WBC—white blood cell
RBUS—renal and bladder ultrasonography
VCUG—voiding cystourethrography

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abstract

FREE

OBJECTIVE: To revise the American Academy of Pediatrics practice parameter regarding the diagnosis and management of initial urinary tract infections (UTIs) in febrile infants and young children.

METHODS: Analysis of the medical literature published since the last version of the guideline was supplemented by analysis of data provided by authors of recent publications. The strength of evidence supporting each recommendation and the strength of the recommendation were assessed and graded.

RESULTS: Diagnosis is made on the basis of the presence of both pyuria and at least 50 000 colonies per mL of a single uropathogenic organism in an appropriately collected specimen of urine. After 7 to 14 days of antimicrobial treatment, close clinical follow-up monitoring should be maintained to permit prompt diagnosis and treatment of recurrent infections. Ultrasonography of the kidneys and bladder should be performed to detect anatomic abnormalities. Data from the most recent 6 studies do not support the use of antimicrobial prophylaxis to prevent febrile recurrent UTI in infants without vesicoureteral reflux (VUR) or with grade I to IV VUR. Therefore, a voiding cystourethrography (VCUG) is not recommended routinely after the first UTI; VCUG is indicated if renal and bladder ultrasonography reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy and in other atypical or complex clinical circumstances. VCUG should also be performed if there is a recurrence of a febrile UTI. The recommendations in this guideline do not indicate an exclusive course of treatment or serve as a standard of care; variations may be appropriate. Recommendations about antimicrobial prophylaxis and implications for performance of VCUG are based on currently available evidence. As with all American Academy of Pediatrics clinical guidelines, the recommendations will be reviewed routinely and incorporate new evidence, such as data from the Randomized Intervention for Children With Vesicoureteral Reflux (RIVUR) study.

CONCLUSIONS: Changes in this revision include criteria for the diagnosis of UTI and recommendations for imaging. *Pediatrics* 2011;128:595–610

INTRODUCTION

Since the early 1970s, occult bacteremia has been the major focus of concern for clinicians evaluating febrile infants who have no recognizable source of infection. With the introduction of effective conjugate vaccines against *Haemophilus influenzae* type b and *Streptococcus pneumoniae* (which have resulted in dramatic decreases in bacteremia and meningitis), there has been increasing appreciation of the urinary tract as the most frequent site of occult and serious bacterial infections. Because the clinical presentation tends to be nonspecific in infants and reliable urine specimens for culture cannot be obtained without invasive methods (urethral catheterization or suprapubic aspiration [SPA]), diagnosis and treatment may be delayed. Most experimental and clinical data support the concept that delays in the institution of appropriate treatment of pyelonephritis increase the risk of renal damage.^{1,2}

This clinical practice guideline is a revision of the practice parameter published by the American Academy of Pediatrics (AAP) in 1999.³ It was developed by a subcommittee of the Steering Committee on Quality Improvement and Management that included physicians with expertise in the fields of academic general pediatrics, epidemiology and informatics, pediatric infectious diseases, pediatric nephrology, pediatric practice, pediatric radiology, and pediatric urology. The AAP funded the development of this guideline; none of the participants had any financial conflicts of interest. The guideline was reviewed by multiple groups within the AAP (7 committees, 1 council, and 9 sections) and 5 external organizations in the United States and Canada. The guideline will be reviewed and/or revised in 5 years, unless new evidence emerges that warrants revision sooner. The guideline is intended

for use in a variety of clinical settings (eg, office, emergency department, or hospital) by clinicians who treat infants and young children. This text is a summary of the analysis. The data on which the recommendations are based are included in a companion technical report.⁴

Like the 1999 practice parameter, this revision focuses on the diagnosis and management of initial urinary tract infections (UTIs) in febrile infants and young children (2–24 months of age) who have no obvious neurologic or anatomic abnormalities known to be associated with recurrent UTI or renal damage. (For simplicity, in the remainder of this guideline the phrase “febrile infants” is used to indicate febrile infants and young children 2–24 months of age.) The lower and upper age limits were selected because studies on infants with unexplained fever generally have used these age limits and have documented that the prevalence of UTI is high (~5%) in this age group. In those studies, fever was defined as temperature of at least 38.0°C ($\geq 100.4^{\circ}\text{F}$); accordingly, this definition of fever is used in this guideline. Neonates and infants less than 2 months of age are excluded, because there are special considerations in this age group that may limit the application of evidence derived from the studies of 2- to 24-month-old children. Data are insufficient to determine whether the evidence generated from studies of infants 2 to 24 months of age applies to children more than 24 months of age.

METHODS

To provide evidence for the guideline, 2 literature searches were conducted, that is, a surveillance of Medline-listed literature over the past 10 years for significant changes since the guideline was published and a systematic review of the literature on the effective-

ness of prophylactic antimicrobial therapy to prevent recurrence of febrile UTI/pyelonephritis in children with vesicoureteral reflux (VUR). The latter was based on the new and growing body of evidence questioning the effectiveness of antimicrobial prophylaxis to prevent recurrent febrile UTI in children with VUR. To explore this particular issue, the literature search was expanded to include trials published since 1993 in which antimicrobial prophylaxis was compared with no treatment or placebo treatment for children with VUR. Because all except 1 of the recent randomized controlled trials (RCTs) of the effectiveness of prophylaxis included children more than 24 months of age and some did not provide specific data according to grade of VUR, the authors of the 6 RCTs were contacted; all provided raw data from their studies specifically addressing infants 2 to 24 months of age, according to grade of VUR. Meta-analysis of these data was performed.

Results from the literature searches and meta-analyses were provided to committee members. Issues were raised and discussed until consensus was reached regarding recommendations. The quality of evidence supporting each recommendation and the strength of the recommendation were assessed by the committee member most experienced in informatics and epidemiology and were graded according to AAP policy⁵ (Fig 1).

The subcommittee formulated 7 recommendations, which are presented in the text in the order in which a clinician would use them when evaluating and treating a febrile infant, as well as in algorithm form in the Appendix. This clinical practice guideline is not intended to be a sole source of guidance for the treatment of febrile infants with UTIs. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or to

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation	
	Recommendation	

FIGURE 1
AAP evidence strengths.

establish an exclusive protocol for the care of all children with this condition.

DIAGNOSIS

Action Statement 1

If a clinician decides that a febrile infant with no apparent source for the fever requires antimicrobial therapy to be administered because of ill appearance or another pressing reason, the clinician should ensure that a urine specimen is obtained for both culture and urinalysis before an antimicrobial agent is administered; the specimen needs to be obtained through catheterization or SPA, because the diagnosis of UTI cannot be established reliably through culture of urine collected in a bag (evidence quality: A; strong recommendation).

When evaluating febrile infants, clinicians make a subjective assessment of the degree of illness or toxicity, in addition to seeking an explanation for the fever. This clinical assessment determines whether antimicrobial therapy should be initiated promptly and affects the diagnostic process regarding UTI. If the clinician determines that the degree of illness warrants immediate antimicrobial therapy, then a urine specimen suitable for culture should be obtained through catheterization or SPA before antimicrobial agents are

administered, because the antimicrobial agents commonly prescribed in such situations would almost certainly obscure the diagnosis of UTI.

SPA has been considered the standard method for obtaining urine that is uncontaminated by perineal flora. Variable success rates for obtaining urine have been reported (23%–90%).^{6–8} When ultrasonographic guidance is used, success rates improve.^{9,10} The technique has limited risks, but technical expertise and experience are required, and many parents and physicians perceive the procedure as unacceptably invasive, compared with catheterization. However, there may be no acceptable alternative to SPA for boys with moderate or severe phimosis or girls with tight labial adhesions.

Urine obtained through catheterization for culture has a sensitivity of 95% and a specificity of 99%, compared with that obtained through SPA.^{7,11,12} The techniques required for catheterization and SPA are well described.¹³ When catheterization or SPA is being attempted, the clinician should have a sterile container ready to collect a urine specimen, because the preparation for the procedure may stimulate the child to void. Whether the urine is obtained through catheterization or is voided, the first few drops should be allowed to fall outside the sterile con-

tainer, because they may be contaminated by bacteria in the distal urethra.

Cultures of urine specimens collected in a bag applied to the perineum have an unacceptably high false-positive rate and are valid only when they yield negative results.^{6,14–16} With a prevalence of UTI of 5% and a high rate of false-positive results (specificity: ~63%), a “positive” culture result for urine collected in a bag would be a false-positive result 88% of the time. For febrile boys, with a prevalence of UTI of 2%, the rate of false-positive results is 95%; for circumcised boys, with a prevalence of UTI of 0.2%, the rate of false-positive results is 99%. Therefore, in cases in which antimicrobial therapy will be initiated, catheterization or SPA is required to establish the diagnosis of UTI.

- Aggregate quality of evidence: A (diagnostic studies on relevant populations).
- Benefits: A missed diagnosis of UTI can lead to renal scarring if left untreated; overdiagnosis of UTI can lead to overtreatment and unnecessary and expensive imaging. Once antimicrobial therapy is initiated, the opportunity to make a definitive diagnosis is lost; multiple studies of antimicrobial therapy have shown that the urine may be rapidly sterilized.
- Harms/risks/costs: Catheterization is invasive.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Once antimicrobial therapy has begun, the opportunity to make a definitive diagnosis is lost. Therefore, it is important to have the most-accurate test for UTI performed initially.
- Role of patient preferences: There is no evidence regarding patient preferences for bag versus catheterized urine. However, bladder tap has

been shown to be more painful than urethral catheterization.

- Exclusions: None.
- Intentional vagueness: The basis of the determination that antimicrobial therapy is needed urgently is not specified, because variability in clinical judgment is expected; considerations for individual patients, such as availability of follow-up care, may enter into the decision, and the literature provides only general guidance.
- Policy level: Strong recommendation.

Action Statement 2

If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI (see below for how to assess likelihood).

Action Statement 2a

If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).

Action Statement 2b

If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation). Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis. Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results positive for leukocytes or bacteria), then a urine specimen should

Individual Risk Factors: Girls		Probability of UTI	No. of Factors Present
White race		≤1%	No more than 1
Age < 12 mo		≤2%	No more than 2
Temperature ≥ 39°C			
Fever ≥ 2 d			
Absence of another source of infection			

Individual Risk Factors: Boys		Probability of UTI	No. of Factors Present	
			Uncircumcised	Circumcised
Nonblack race		≤1%	a	No more than 2
Temperature ≥ 39°C		≤2%	None	No more than 3
Fever > 24 h				
Absence of another source of infection				

FIGURE 2

Probability of UTI Among Febrile Infant Girls²⁸ and Infant Boys³⁰ According to Number of Findings Present. ^aProbability of UTI exceeds 1% even with no risk factors other than being uncircumcised.

be obtained through catheterization or SPA and cultured; if urinalysis of fresh (<1 hour since void) urine yields negative leukocyte esterase and nitrite test results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that negative urinalysis results do not rule out a UTI with certainty.

If the clinician determines that the degree of illness does not require immediate antimicrobial therapy, then the likelihood of UTI should be assessed. As noted previously, the overall prevalence of UTI in febrile infants who have no source for their fever evident on the basis of history or physical examination results is approximately 5%,^{17,18} but it is possible to identify groups with higher-than-average likelihood and some with lower-than-average likelihood. The prevalence of UTI among febrile infant girls is more than twice that among febrile infant boys (relative risk: 2.27). The rate for uncircumcised boys is 4 to 20 times higher than that for circumcised boys, whose rate of UTI is only 0.2% to 0.4%.^{19–24} The presence of another, clinically obvious source of infection reduces the likelihood of UTI by one-half.²⁵

In a survey asking, “What yield is required to warrant urine culture in febrile infants?” the threshold was less

than 1% for 10.4% of academicians and 11.7% for practitioners²⁶; when the threshold was increased to 1% to 3%, 67.5% of academicians and 45.7% of practitioners considered the yield sufficiently high to warrant urine culture. Therefore, attempting to operationalize “low likelihood” (ie, below a threshold that warrants a urine culture) does not produce an absolute percentage; clinicians will choose a threshold depending on factors such as their confidence that contact will be maintained through the illness (so that a specimen can be obtained at a later time) and comfort with diagnostic uncertainty. Fig 2 indicates the number of risk factors associated with threshold probabilities of UTI of at least 1% and at least 2%.

In a series of studies, Gorelick, Shaw, and colleagues^{27–29} derived and validated a prediction rule for febrile infant girls on the basis of 5 risk factors, namely, white race, age less than 12 months, temperature of at least 39°C, fever for at least 2 days, and absence of another source of infection. This prediction rule, with sensitivity of 88% and specificity of 30%, permits some infant girls to be considered in a low-likelihood group (Fig 2). For example, of girls with no identifiable source of infection, those who are nonwhite and more than 12 months of age with a recent onset (<2 days) of low-

grade fever ($<39^{\circ}\text{C}$) have less than a 1% probability of UTI; each additional risk factor increases the probability. It should be noted, however, that some of the factors (eg, duration of fever) may change during the course of the illness, excluding the infant from a low-likelihood designation and prompting testing as described in action statement 2a.

As demonstrated in Fig 2, the major risk factor for febrile infant boys is whether they are circumcised. The probability of UTI can be estimated on the basis of 4 risk factors, namely, nonblack race, temperature of at least 39°C , fever for more than 24 hours, and absence of another source of infection.^{4,30}

If the clinician determines that the infant does not require immediate antimicrobial therapy and a urine specimen is desired, then often a urine collection bag affixed to the perineum is used. Many clinicians think that this collection technique has a low contamination rate under the following circumstances: the patient's perineum is properly cleansed and rinsed before application of the collection bag, the urine bag is removed promptly after urine is voided into the bag, and the specimen is refrigerated or processed immediately. Even if contamination from the perineal skin is minimized, however, there may be significant contamination from the vagina in girls or the prepuce in uncircumcised boys, the 2 groups at highest risk of UTI. A "positive" culture result from a specimen collected in a bag cannot be used to document a UTI; confirmation requires culture of a specimen collected through catheterization or SPA. Because there may be substantial delay waiting for the infant to void and a second specimen, obtained through catheterization, may be necessary if the urinalysis suggests the possibility of UTI, many clinicians prefer to obtain a

TABLE 1 Sensitivity and Specificity of Components of Urinalysis, Alone and in Combination

Test	Sensitivity (Range), %	Specificity (Range), %
Leukocyte esterase test	83 (67–94)	78 (64–92)
Nitrite test	53 (15–82)	98 (90–100)
Leukocyte esterase or nitrite test positive	93 (90–100)	72 (58–91)
Microscopy, WBCs	73 (32–100)	81 (45–98)
Microscopy, bacteria	81 (16–99)	83 (11–100)
Leukocyte esterase test, nitrite test, or microscopy positive	99.8 (99–100)	70 (60–92)

definitive urine specimen through catheterization initially.

- Aggregate quality of evidence: A (diagnostic studies on relevant populations).
- Benefits: Accurate diagnosis of UTI can prevent the spread of infection and renal scarring; avoiding overdiagnosis of UTI can prevent overtreatment and unnecessary and expensive imaging.
- Harms/risks/costs: A small proportion of febrile infants, considered at low likelihood of UTI, will not receive timely identification and treatment of their UTIs.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: There is a risk of UTI sufficiently low to forestall further evaluation.
- Role of patient preferences: The choice of option 1 or option 2 and the threshold risk of UTI warranting obtaining a urine specimen may be influenced by parents' preference to avoid urethral catheterization (if a bag urine sample yields negative urinalysis results) versus timely evaluation (obtaining a definitive specimen through catheterization).
- Exclusions: Because it depends on a range of patient- and physician-specific considerations, the precise threshold risk of UTI warranting obtaining a urine specimen is left to the clinician but is below 3%.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

Action Statement 3

To establish the diagnosis of UTI, clinicians should require *both* urinalysis results that suggest infection (pyuria and/or bacteriuria) and the presence of at least 50 000 colony-forming units (CFUs) per mL of a uropathogen cultured from a urine specimen obtained through catheterization or SPA (evidence quality: C; recommendation).

Urinalysis

General Considerations

Urinalysis cannot substitute for urine culture to document the presence of UTI but needs to be used in conjunction with culture. Because urine culture results are not available for at least 24 hours, there is considerable interest in tests that may predict the results of the urine culture and enable presumptive therapy to be initiated at the first encounter. Urinalysis can be performed on any specimen, including one collected from a bag applied to the perineum. However, the specimen must be fresh (<1 hour after voiding with maintenance at room temperature or <4 hours after voiding with refrigeration), to ensure sensitivity and specificity of the urinalysis. The tests that have received the most attention are biochemical analyses of leukocyte esterase and nitrite through a rapid dipstick method and urine microscopic examination for white blood cells (WBCs) and bacteria (Table 1).

Urine dipsticks are appealing, because they provide rapid results, do not require microscopy, and are eligible for a waiver under the Clinical Laboratory Improvement Amendments. They indicate the presence of leukocyte esterase (as a surrogate marker for pyuria) and urinary nitrite (which is converted from dietary nitrates in the presence of most Gram-negative enteric bacteria in the urine). The conversion of dietary nitrates to nitrites by bacteria requires approximately 4 hours in the bladder.³¹ The performance characteristics of both leukocyte esterase and nitrite tests vary according to the definition used for positive urine culture results, the age and symptoms of the population being studied, and the method of urine collection.

Nitrite Test

A nitrite test is not a sensitive marker for children, particularly infants, who empty their bladders frequently. Therefore, negative nitrite test results have little value in ruling out UTI. Moreover, not all urinary pathogens reduce nitrate to nitrite. The test is helpful when the result is positive, however, because it is highly specific (ie, there are few false-positive results).³²

Leukocyte Esterase Test

The sensitivity of the leukocyte esterase test is 94% when it is used in the context of clinically suspected UTI. Overall, the reported sensitivity in various studies is lower (83%), because the results of leukocyte esterase tests were related to culture results without exclusion of individuals with asymptomatic bacteriuria. The absence of leukocyte esterase in the urine of individuals with asymptomatic bacteriuria is an advantage of the test, rather than a limitation, because it distinguishes individuals with asymptomatic bacteriuria from those with true UTI.

The specificity of the leukocyte esterase test (average: 72% [range:

64%–92%]) generally is not as good as the sensitivity, which reflects the non-specificity of pyuria in general. Accordingly, positive leukocyte esterase test results should be interpreted with caution, because false-positive results are common. With numerous conditions other than UTI, including fever resulting from other conditions (eg, streptococcal infections or Kawasaki disease), and after vigorous exercise, WBCs may be found in the urine. Therefore, a finding of pyuria by no means confirms that an infection of the urinary tract is present.

The absence of pyuria in children with true UTIs is rare, however. It is theoretically possible if a febrile child is assessed before the inflammatory response has developed, but the inflammatory response to a UTI produces both fever and pyuria; therefore, children who are being evaluated because of fever should already have WBCs in their urine. More likely explanations for significant bacteriuria in culture in the absence of pyuria include contaminated specimens, insensitive criteria for pyuria, and asymptomatic bacteriuria. In most cases, when true UTI has been reported to occur in the absence of pyuria, the definition of pyuria has been at fault. The standard method of assessing pyuria has been centrifugation of the urine and microscopic analysis, with a threshold of 5 WBCs per high-power field (~25 WBCs per μL). If a counting chamber is used, however, the finding of at least 10 WBCs per μL in uncentrifuged urine has been demonstrated to be more sensitive³³ and performs well in clinical situations in which the standard method does not, such as with very young infants.³⁴

An important cause of bacteriuria in the absence of pyuria is asymptomatic bacteriuria. Asymptomatic bacteriuria often is associated with school-aged and older girls,³⁵ but it can be present

during infancy. In a study of infants 2 to 24 months of age, 0.7% of afebrile girls had 3 successive urine cultures with 10^5 CFUs per mL of a single uropathogen.²⁶ Asymptomatic bacteriuria can be easily confused with true UTI in a febrile infant but needs to be distinguished, because studies suggest that antimicrobial treatment may do more harm than good.³⁶ The key to distinguishing true UTI from asymptomatic bacteriuria is the presence of pyuria.

Microscopic Analysis for Bacteriuria

The presence of bacteria in a fresh, Gram-stained specimen of uncentrifuged urine correlates with 10^5 CFUs per mL in culture.³⁷ An “enhanced urinalysis,” combining the counting chamber assessment of pyuria noted previously with Gram staining of drops of uncentrifuged urine, with a threshold of at least 1 Gram-negative rod in 10 oil immersion fields, has greater sensitivity, specificity, and positive predictive value than does the standard urinalysis³³ and is the preferred method of urinalysis when appropriate equipment and personnel are available.

Automated Urinalysis

Automated methods to perform urinalysis are now being used in many hospitals and laboratories. Image-based systems use flow imaging analysis technology and software to classify particles in uncentrifuged urine specimens rapidly.³⁸ Results correlate well with manual methods, especially for red blood cells, WBCs, and squamous epithelial cells. In the future, this may be the most common method by which urinalysis is performed in laboratories.

Culture

The diagnosis of UTI is made on the basis of quantitative urine culture results in addition to evidence of pyuria and/or bacteriuria. Urine specimens should be processed as expeditiously as

possible. If the specimen is not processed promptly, then it should be refrigerated to prevent the growth of organisms that can occur in urine at room temperature; for the same reason, specimens that require transportation to another site for processing should be transported on ice. A properly collected urine specimen should be inoculated on culture medium that will allow identification of urinary tract pathogens.

Urine culture results are considered positive or negative on the basis of the number of CFUs that grow on the culture medium.³⁶ Definition of significant colony counts with regard to the method of collection considers that the distal urethra and periurethral area are commonly colonized by the same bacteria that may cause UTI; therefore, a low colony count may be present in a specimen obtained through voiding or catheterization when bacteria are not present in bladder urine. Definitions of positive and negative culture results are operational and not absolute. The time the urine resides in the bladder (bladder incubation time) is an important determinant of the magnitude of the colony count. The concept that more than 100 000 CFUs per mL indicates a UTI was based on morning collections of urine from adult women, with comparison of specimens from women without symptoms and women considered clinically to have pyelonephritis; the transition range, in which the proportion of women with pyelonephritis exceeded the proportion of women without symptoms, was 10 000 to 100 000 CFUs per mL.³⁹ In most instances, an appropriate threshold to consider bacteriuria “significant” in infants and children is the presence of at least 50 000 CFUs per mL of a single urinary pathogen.⁴⁰ (Organisms such as *Lactobacillus* spp, coagulase-negative staphylococci, and *Corynebacterium*

spp are not considered clinically relevant urine isolates for otherwise healthy, 2- to 24-month-old children.) Reducing the threshold from 100 000 CFUs per mL to 50 000 CFUs per mL would seem to increase the sensitivity of culture at the expense of decreased specificity; however, because the proposed criteria for UTI now include evidence of pyuria in addition to positive culture results, infants with “positive” culture results alone will be recognized as having asymptomatic bacteriuria rather than a true UTI. Some laboratories report growth only in the following categories: 0 to 1000, 1000 to 10 000, 10 000 to 100 000, and more than 100 000 CFUs per mL. In such cases, results in the 10 000 to 100 000 CFUs per mL range need to be evaluated in context, such as whether the urinalysis findings support the diagnosis of UTI and whether the organism is a recognized uropathogen.

Alternative culture methods, such as dipslides, may have a place in the office setting; sensitivity is reported to be in the range of 87% to 100%, and specificity is reported to be 92% to 98%, but dipslides cannot specify the organism or antimicrobial sensitivities.⁴¹ Practices that use dipslides should do so in collaboration with a certified laboratory for identification and sensitivity testing or, in the absence of such results, may need to perform “test of cure” cultures after 24 hours of treatment.

- Aggregate quality of evidence: C (observational studies).
- Benefits: Accurate diagnosis of UTI can prevent the spread of infection and renal scarring; avoiding overdiagnosis of UTI can prevent overtreatment and unnecessary and expensive imaging. These criteria reduce the likelihood of overdiagnosis of UTI in infants with asymptomatic bacteriuria or contaminated specimens.

- Harms/risks/costs: Stringent diagnostic criteria may miss a small number of UTIs.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Treatment of asymptomatic bacteriuria may be harmful.
- Role of patient preferences: We assume that parents prefer no action in the absence of a UTI (avoiding false-positive results) over a very small chance of missing a UTI.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

MANAGEMENT

Action Statement 4

Action Statement 4a

When initiating treatment, the clinician should base the choice of route of administration on practical considerations. Initiating treatment orally or parenterally is equally efficacious. The clinician should base the choice of agent on local antimicrobial sensitivity patterns (if available) and should adjust the choice according to sensitivity testing of the isolated uropathogen (evidence quality: A; strong recommendation).

Action Statement 4b

The clinician should choose 7 to 14 days as the duration of antimicrobial therapy (evidence quality: B; recommendation).

The goals of treatment of acute UTI are to eliminate the acute infection, to prevent complications, and to reduce the likelihood of renal damage. Most children can be treated orally.^{42–44} Patients whom clinicians judge to be “toxic” or who are unable to retain oral intake (including medications) should receive an antimicrobial agent parenter-

TABLE 2 Some Empiric Antimicrobial Agents for Parenteral Treatment of UTI

Antimicrobial Agent	Dosage
Ceftriaxone	75 mg/kg, every 24 h
Cefotaxime	150 mg/kg per d, divided every 6–8 h
Ceftazidime	100–150 mg/kg per d, divided every 8 h
Gentamicin	7.5 mg/kg per d, divided every 8 h
Tobramycin	5 mg/kg per d, divided every 8 h
Piperacillin	300 mg/kg per d, divided every 6–8 h

ally (Table 2) until they exhibit clinical improvement, generally within 24 to 48 hours, and are able to retain orally administered fluids and medications. In a study of 309 febrile infants with UTIs, only 3 (1%) were deemed too ill to be assigned randomly to either parenteral or oral treatment.⁴² Parenteral administration of an antimicrobial agent also should be considered when compliance with obtaining an antimicrobial agent and/or administering it orally is uncertain. The usual choices for oral treatment of UTIs include a cephalosporin, amoxicillin plus clavulanic acid, or trimethoprim-sulfamethoxazole (Table 3). It is essential to know local patterns of susceptibility of coliforms to antimicrobial agents, particularly trimethoprim-sulfamethoxazole and cephalexin, because there is substantial geographic variability that needs to be taken into account during selection of an antimicrobial agent before sensitivity results are available. Agents that are excreted in the urine but do not achieve therapeutic concentrations in the bloodstream, such as nitrofurantoin, should not be used to treat febrile infants with UTIs, because parenchymal and serum antimicrobial concentrations may be insufficient to treat pyelonephritis or urosepsis.

Whether the initial route of administration of the antimicrobial agent is oral or parenteral (then changed to oral),

TABLE 3 Some Empiric Antimicrobial Agents for Oral Treatment of UTI

Antimicrobial Agent	Dosage
Amoxicillin-clavulanate	20–40 mg/kg per d in 3 doses
Sulfonamide	
Trimethoprim-sulfamethoxazole	6–12 mg/kg trimethoprim and 30–60 mg/kg sulfamethoxazole per d in 2 doses
Sulfisoxazole	120–150 mg/kg per d in 4 doses
Cephalosporin	
Cefixime	8 mg/kg per d in 1 dose
Cefpodoxime	10 mg/kg per d in 2 doses
Cefprozil	30 mg/kg per d in 2 doses
Cefuroxime axetil	20–30 mg/kg per d in 2 doses
Cephalexin	50–100 mg/kg per d in 4 doses

the total course of therapy should be 7 to 14 days. The committee attempted to identify a single, preferred, evidence-based duration, rather than a range, but data comparing 7, 10, and 14 days directly were not found. There is evidence that 1- to 3-day courses for febrile UTIs are inferior to courses in the recommended range; therefore, the minimal duration selected should be 7 days.

- Aggregate quality of evidence: A/B (RCTs).
- Benefits: Adequate treatment of UTI can prevent the spread of infection and renal scarring. Outcomes of short courses (1–3 d) are inferior to those of 7- to 14-d courses.
- Harms/risks/costs: There are minimal harm and minor cost effects of antimicrobial choice and duration of therapy.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Adjusting antimicrobial choice on the basis of available data and treating according to best evidence will minimize cost and consequences of failed or unnecessary treatment.
- Role of patient preferences: It is assumed that parents prefer the most-effective treatment and the least amount of medication that ensures effective treatment.
- Exclusions: None.
- Intentional vagueness: No evidence

distinguishes the benefit of treating 7 vs 10 vs 14 days, and the range is allowable.

- Policy level: Strong recommendation/recommendation.

Action Statement 5

Febrile infants with UTIs should undergo renal and bladder ultrasonography (RBUS) (evidence quality: C; recommendation).

The purpose of RBUS is to detect anatomic abnormalities that require further evaluation, such as additional imaging or urologic consultation. RBUS also provides an evaluation of the renal parenchyma and an assessment of renal size that can be used to monitor renal growth. The yield of actionable findings is relatively low.^{45,46} Widespread application of prenatal ultrasonography clearly has reduced the prevalence of previously unsuspected obstructive uropathy in infants, but the consequences of prenatal screening with respect to the risk of renal abnormalities in infants with UTIs have not yet been well defined. There is considerable variability in the timing and quality of prenatal ultrasonograms, and the report of “normal” ultrasonographic results cannot necessarily be relied on to dismiss completely the possibility of a structural abnormality unless the study was a detailed anatomic survey (with measurements), was performed during the third tri-

mester, and was performed and interpreted by qualified individuals.⁴⁷

The timing of RBUS depends on the clinical situation. RBUS is recommended during the first 2 days of treatment to identify serious complications, such as renal or perirenal abscesses or pyonephrosis associated with obstructive uropathy when the clinical illness is unusually severe or substantial clinical improvement is not occurring. For febrile infants with UTIs who demonstrate substantial clinical improvement, however, imaging does not need to occur early during the acute infection and can even be misleading; animal studies demonstrate that *Escherichia coli* endotoxin can produce dilation during acute infection, which could be confused with hydronephrosis, pyonephrosis, or obstruction.⁴⁸ Changes in the size and shape of the kidneys and the echogenicity of renal parenchyma attributable to edema also are common during acute infection. The presence of these abnormalities makes it inappropriate to consider RBUS performed early during acute infection to be a true baseline study for later comparisons in the assessment of renal growth.

Nuclear scanning with technetium-labeled dimercaptosuccinic acid has greater sensitivity for detection of acute pyelonephritis and later scarring than does either RBUS or voiding cystourethrography (VCUG). The scanning is useful in research, because it ensures that all subjects in a study have pyelonephritis to start with and it permits assessment of later renal scarring as an outcome measure. The findings on nuclear scans rarely affect acute clinical management, however, and are not recommended as part of routine evaluation of infants with their first febrile UTI. The radiation dose to the patient during dimercaptosuccinic acid scanning is generally low (~1 mSv),⁴⁹ although it may be increased in

children with reduced renal function. The radiation dose from dimercaptosuccinic acid is additive with that of VCUG when both studies are performed.⁵⁰ The radiation dose from VCUG depends on the equipment that is used (conventional versus pulsed digital fluoroscopy) and is related directly to the total fluoroscopy time. Moreover, the total exposure for the child will be increased when both acute and follow-up studies are obtained. The lack of exposure to radiation is a major advantage of RBUS, even with recognition of the limitations of this modality that were described previously.

- Aggregate quality of evidence: C (observational studies).
- Benefits: RBUS in this population will yield abnormal results in ~15% of cases, and 1% to 2% will have abnormalities that would lead to action (eg, additional evaluation, referral, or surgery).
- Harms/risks/costs: Between 2% and 3% will be false-positive results, leading to unnecessary and invasive evaluations.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The seriousness of the potentially correctable abnormalities in 1% to 2%, coupled with the absence of physical harm, was judged sufficiently important to tip the scales in favor of testing.
- Role of patient preferences: Because ultrasonography is noninvasive and poses minimal risk, we assume that parents will prefer RBUS over taking even a small risk of missing a serious and correctable condition.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

Action Statement 6

Action Statement 6a

VCUG should not be performed routinely after the first febrile UTI; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances (evidence quality B; recommendation).

Action Statement 6b

Further evaluation should be conducted if there is a recurrence of febrile UTI (evidence quality: X; recommendation).

For the past 4 decades, the strategy to protect the kidneys from further damage after an initial UTI has been to detect childhood genitourinary abnormalities in which recurrent UTI could increase renal damage. The most common of these is VUR, and VCUG is used to detect this. Management included continuous antimicrobial administration as prophylaxis and surgical intervention if VUR was persistent or recurrences of infection were not prevented with an antimicrobial prophylaxis regimen; some have advocated surgical intervention to correct high-grade reflux even when infection has not recurred. However, it is clear that there are a significant number of infants who develop pyelonephritis in whom VUR cannot be demonstrated, and the effectiveness of antimicrobial prophylaxis for patients who have VUR has been challenged in the past decade. Several studies have suggested that prophylaxis does not confer the desired benefit of preventing recurrent febrile UTI.^{51–55} If prophylaxis is, in fact, not beneficial and VUR is not required for development of pyelonephritis, then the rationale for performing VCUG routinely after an initial febrile UTI must be questioned.

RCTs of the effectiveness of prophylaxis performed to date generally included children more than 24 months of age, and some did not provide complete data according to grade of VUR. These 2 factors have compromised meta-analyses. To ensure direct comparisons, the committee contacted the 6 researchers who had conducted the most recent RCTs and requested raw data from their studies.^{51–56} All complied, which permitted the creation of a data set with data for 1091 infants 2 to 24 months of age according to grade of VUR. A χ^2 analysis (2-tailed) and a formal meta-analysis did not detect a statistically significant benefit of prophylaxis in preventing recurrence of febrile UTI/pyelonephritis in infants without reflux or those with grades I, II, III, or IV VUR (Table 4 and Fig 3). Only 5 infants with grade V VUR were included in the RCTs; therefore, data for those infants are not included in Table 4 or Fig 3.

The proportion of infants with high-grade VUR among all infants with febrile UTIs is small. Data adapted from current studies (Table 5) indicate that, of a hypothetical cohort of 100 infants with febrile UTIs, only 1 has grade V VUR; 99 do not. With a practice of waiting for a second UTI to perform VCUG, only 10 of the 100 would need to undergo the procedure and the 1 with grade V VUR would be identified. (It also is possible that the 1 infant with grade V VUR might have been identified after the first UTI on the basis of abnormal RBUS results that prompted VCUG to be performed.) Data to quantify additional potential harm to an infant who is not revealed to have high-grade VUR until a second UTI are not precise but suggest that the increment is insufficient to justify routinely subjecting all infants with an initial febrile UTI to VCUG (Fig 4). To minimize any harm incurred by that infant, attempts have been made to identify, at the time of

TABLE 4 Recurrences of Febrile UTI/Pyelonephritis in Infants 2 to 24 Months of Age With and Without Antimicrobial Prophylaxis, According to Grade of VUR

Reflux Grade	Prophylaxis		No Prophylaxis		<i>P</i>
	No. of Recurrences	Total <i>N</i>	No. of Recurrences	Total <i>N</i>	
None	7	210	11	163	.15
I	2	37	2	35	1.00
II	11	133	10	124	.95
III	31	140	40	145	.29
IV	16	55	21	49	.14

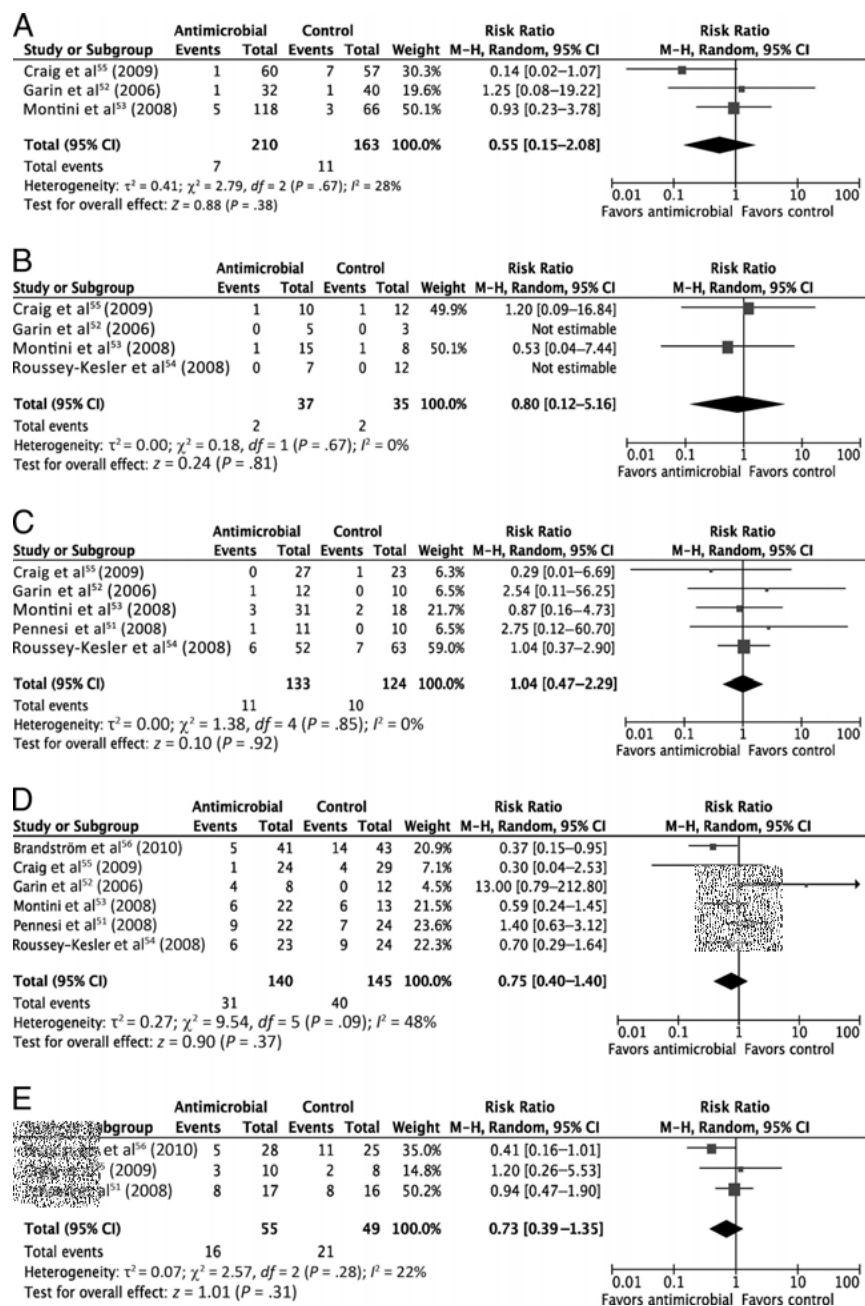
the initial UTI, those who have the greatest likelihood of having high-grade VUR. Unfortunately, there are no clinical or laboratory indicators that have been demonstrated to identify infants with high-grade VUR. Indications for VCUG have been proposed on the basis of consensus in the absence of data⁵⁷; the predictive value of any of the indications for VCUG proposed in this manner is not known.

The level of evidence supporting routine imaging with VCUG was deemed insufficient at the time of the 1999 practice parameter to receive a recommendation, but the consensus of the subcommittee was to “strongly encourage” imaging studies. The position of the current subcommittee reflects the new evidence demonstrating antimicrobial prophylaxis not to be effective as presumed previously. Moreover, prompt diagnosis and effective treatment of a febrile UTI recurrence may be of greater importance regardless of whether VUR is present or the child is receiving antimicrobial prophylaxis. A national study (the Randomized Intervention for Children With Vesicoureteral Reflux study) is currently in progress to identify the effects of a prophylactic antimicrobial regimen for children 2 months to 6 years of age who have experienced a UTI, and it is anticipated to provide additional important data⁵⁸ (see Areas for Research).

Action Statement 6a

- Aggregate quality of evidence: B (RCTs).

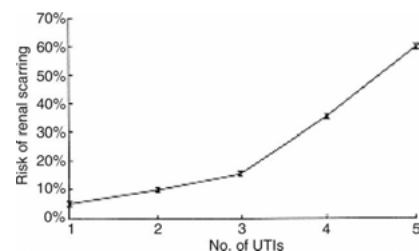
- Benefits: This avoids, for the vast majority of febrile infants with UTIs, radiation exposure (of particular concern near the ovaries in girls), expense, and discomfort.
- Harms/risks/costs: Detection of a small number of cases of high-grade reflux and correctable abnormalities is delayed.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The risks associated with radiation (plus the expense and discomfort of the procedure) for the vast majority of infants outweigh the risk of delaying the detection of the few with correctable abnormalities until their second UTI.
- Role of patient preferences: The judgment of parents may come into play, because VCUG is an uncomfortable procedure involving radiation exposure. In some cases, parents may prefer to subject their children to the procedure even when the chance of benefit is both small and uncertain. Antimicrobial prophylaxis seems to be ineffective in preventing recurrence of febrile UTI/pyelonephritis for the vast majority of infants. Some parents may want to avoid VCUG even after the second UTI. Because the benefit of identifying high-grade reflux is still in some doubt, these preferences should be considered. It is the judgment of the committee that VCUG is indicated after the second UTI.
- Exclusions: None.

**FIGURE 3**

A, Recurrences of febrile UTI/pyelonephritis in 373 infants 2 to 24 months of age without VUR, with and without antimicrobial prophylaxis (based on 3 studies; data provided by Drs Craig, Garin, and Montini). B, Recurrences of febrile UTI/pyelonephritis in 72 infants 2 to 24 months of age with grade I VUR, with and without antimicrobial prophylaxis (based on 4 studies; data provided by Drs Craig, Garin, Montini, and Roussey-Kesler). C, Recurrences of febrile UTI/pyelonephritis in 257 infants 2 to 24 months of age with grade II VUR, with and without antimicrobial prophylaxis (based on 5 studies; data provided by Drs Craig, Garin, Montini, Pennesi, and Roussey-Kesler). D, Recurrences of febrile UTI/pyelonephritis in 285 infants 2 to 24 months of age with grade III VUR, with and without antimicrobial prophylaxis (based on 6 studies; data provided by Drs Brandström, Craig, Garin, Montini, Pennesi, and Roussey-Kesler). E, Recurrences of febrile UTI/pyelonephritis in 104 infants 2 to 24 months of age with grade IV VUR, with and without antimicrobial prophylaxis (based on 3 studies; data provided by Drs Brandström, Craig, and Pennesi). M-H indicates Mantel-Haenszel; CI, confidence interval.

TABLE 5 Rates of VUR According to Grade in Hypothetical Cohort of Infants After First UTI and After Recurrence

	Rate, %	
	After First UTI (N = 100)	After Recurrence (N = 10)
No VUR	65	26
Grades I–III VUR	29	56
Grade IV VUR	5	12
Grade V VUR	1	6

**FIGURE 4**

Relationship between renal scarring and number of bouts of pyelonephritis. Adapted from Jodal.⁵⁹

- Intentional vagueness: None.
- Policy level: Recommendation.

Action Statement 6b

- Aggregate quality of evidence: X (exceptional situation).
- Benefits: VCUg after a second UTI should identify infants with very high-grade reflux.
- Harms/risks/costs: VCUg is an uncomfortable, costly procedure that involves radiation, including to the ovaries of girls.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The committee judged that patients with high-grade reflux and other abnormalities may benefit from interventions to prevent further scarring. Further studies of treatment for grade V VUR are not underway and are unlikely in the near future, because the condition is uncommon and randomization of treatment in this group generally has been considered unethical.

- Role of patient preferences: As mentioned previously, the judgment of parents may come into play, because VCUG is an uncomfortable procedure involving radiation exposure. In some cases, parents may prefer to subject their children to the procedure even when the chance of benefit is both small and uncertain. The benefits of treatment of VUR remain unproven, but the point estimates suggest a small potential benefit. Similarly, parents may want to avoid VCUG even after the second UTI. Because the benefit of identifying high-grade reflux is still in some doubt, these preferences should be considered. It is the judgment of the committee that VCUG is indicated after the second UTI.
- Exclusions: None.
- Intentional vagueness: Further evaluation will likely start with VCUG but may entail additional studies depending on the findings. The details of further evaluation are beyond the scope of this guideline.
- Policy level: Recommendation.
- Aggregate quality of evidence: C (observational studies).
- Benefits: Studies suggest that early treatment of UTI reduces the risk of renal scarring.
- Harms/risks/costs: There may be additional costs and inconvenience to parents with more-frequent visits to the clinician for evaluation of fever.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: None.
- Role of patient preferences: Parents will ultimately make the judgment to seek medical care.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

CONCLUSIONS

The committee formulated 7 key action statements for the diagnosis and treatment of infants and young children 2 to 24 months of age with UTI and unexplained fever. Strategies for diagnosis and treatment depend on whether the clinician determines that antimicrobial therapy is warranted immediately or can be delayed safely until urine culture and urinalysis results are available. Diagnosis is based on the presence of pyuria and at least 50 000 CFUs per mL of a single uropathogen in an appropriately collected specimen of urine; urinalysis alone does not provide a definitive diagnosis. After 7 to 14 days of antimicrobial treatment, close clinical follow-up monitoring should be maintained, with evaluation of the urine during subsequent febrile episodes to permit prompt diagnosis and treatment of recurrent infections. Ultrasonography of the kidneys and bladder should be performed to detect anatomic abnormalities that require further evaluation (eg, additional imaging or urologic consultation). Routine VCUG after the

first UTI is not recommended; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances. VCUG also should be performed if there is a recurrence of febrile UTI.

AREAS FOR RESEARCH

One of the major values of a comprehensive literature review is the identification of areas in which evidence is lacking. The following 8 areas are presented in an order that parallels the previous discussion.

1. The relationship between UTIs in infants and young children and reduced renal function in adults has been established but is not well characterized in quantitative terms. The ideal prospective cohort study from birth to 40 to 50 years of age has not been conducted and is unlikely to be conducted. Therefore, estimates of undesirable outcomes in adulthood, such as hypertension and end-stage renal disease, are based on the mathematical product of probabilities at several steps, each of which is subject to bias and error. Other attempts at decision analysis and thoughtful literature review have recognized the same limitations. Until recently, imaging tools available for assessment of the effects of UTIs have been insensitive. With the imaging techniques now available, it may be possible to identify the relationship of scarring to renal impairment and hypertension.
2. The development of techniques that would permit an alternative to invasive sampling and culture would be valuable for general use. Special attention should be given to infant girls and uncircumcised boys, because urethral catheterization may

Action Statement 7

After confirmation of UTI, the clinician should instruct parents or guardians to seek prompt medical evaluation (ideally within 48 hours) for future febrile illnesses, to ensure that recurrent infections can be detected and treated promptly (evidence quality: C; recommendation).

Early treatment limits renal damage better than late treatment,^{1,2} and the risk of renal scarring increases as the number of recurrences increase (Fig 4).⁵⁹ For these reasons, all infants who have sustained a febrile UTI should have a urine specimen obtained at the onset of subsequent febrile illnesses, so that a UTI can be diagnosed and treated promptly.

be difficult and can produce contaminated specimens and SPA now is not commonly performed. Incubation time, which is inherent in the culture process, results in delayed treatment or presumptive treatment on the basis of tests that lack the desired sensitivity and specificity to replace culture.

3. The role of VUR (and therefore of VCUG) is incompletely understood. It is recognized that pyelonephritis (defined through cortical scintigraphy) can occur in the absence of VUR (defined through VCUG) and that progressive renal scarring (defined through cortical scintigraphy) can occur in the absence of demonstrated VUR.^{52,53} The presumption that antimicrobial prophylaxis is of benefit for individuals with VUR to prevent recurrences of UTI or the development of renal scars is not supported by the aggregate of data from recent studies and currently is the subject of the Randomized Intervention for Children With Vesicoureteral Reflux study.⁵⁸
4. Although the effectiveness of antimicrobial prophylaxis for the prevention of UTI has not been demonstrated, the concept has biological plausibility. Virtually all antimicrobial agents used to treat or to prevent infections of the urinary tract are excreted in the urine in high concentrations. Barriers to the effectiveness of antimicrobial prophylaxis are adherence to a daily regimen, adverse effects associated with the various agents, and the potential for emergence of anti-

microbial resistance. To overcome these issues, evidence of effectiveness with a well-tolerated, safe product would be required, and parents would need sufficient education to understand the value and importance of adherence. A urinary antiseptic, rather than an antimicrobial agent, would be particularly desirable, because it could be taken indefinitely without concern that bacteria would develop resistance. Another possible strategy might be the use of probiotics.

5. Better understanding of the genome (human and bacterial) may provide insight into risk factors (VUR and others) that lead to increased scarring. Blood specimens will be retained from children enrolled in the Randomized Intervention for Children With Vesicoureteral Reflux study, for future examination of genetic determinants of VUR, recurrent UTI, and renal scarring.⁵⁸ VUR is recognized to “run in families,”^{60,61} and multiple investigators are currently engaged in research to identify a genetic basis for VUR. Studies may also be able to distinguish the contribution of congenital dysplasia from acquired scarring attributable to UTI.
6. One of the factors used to assess the likelihood of UTI in febrile infants is race. Data regarding rates among Hispanic individuals are limited and would be useful for prediction rules.
7. This guideline is limited to the initial management of the first UTI in febrile infants 2 to 24 months of age. Some of

the infants will have recurrent UTIs; some will be identified as having VUR or other abnormalities. Further research addressing the optimal course of management in specific situations would be valuable.

8. The optimal duration of antimicrobial treatment has not been determined. RCTs of head-to-head comparisons of various duration would be valuable, enabling clinicians to limit antimicrobial exposure to what is needed to eradicate the offending uropathogen.

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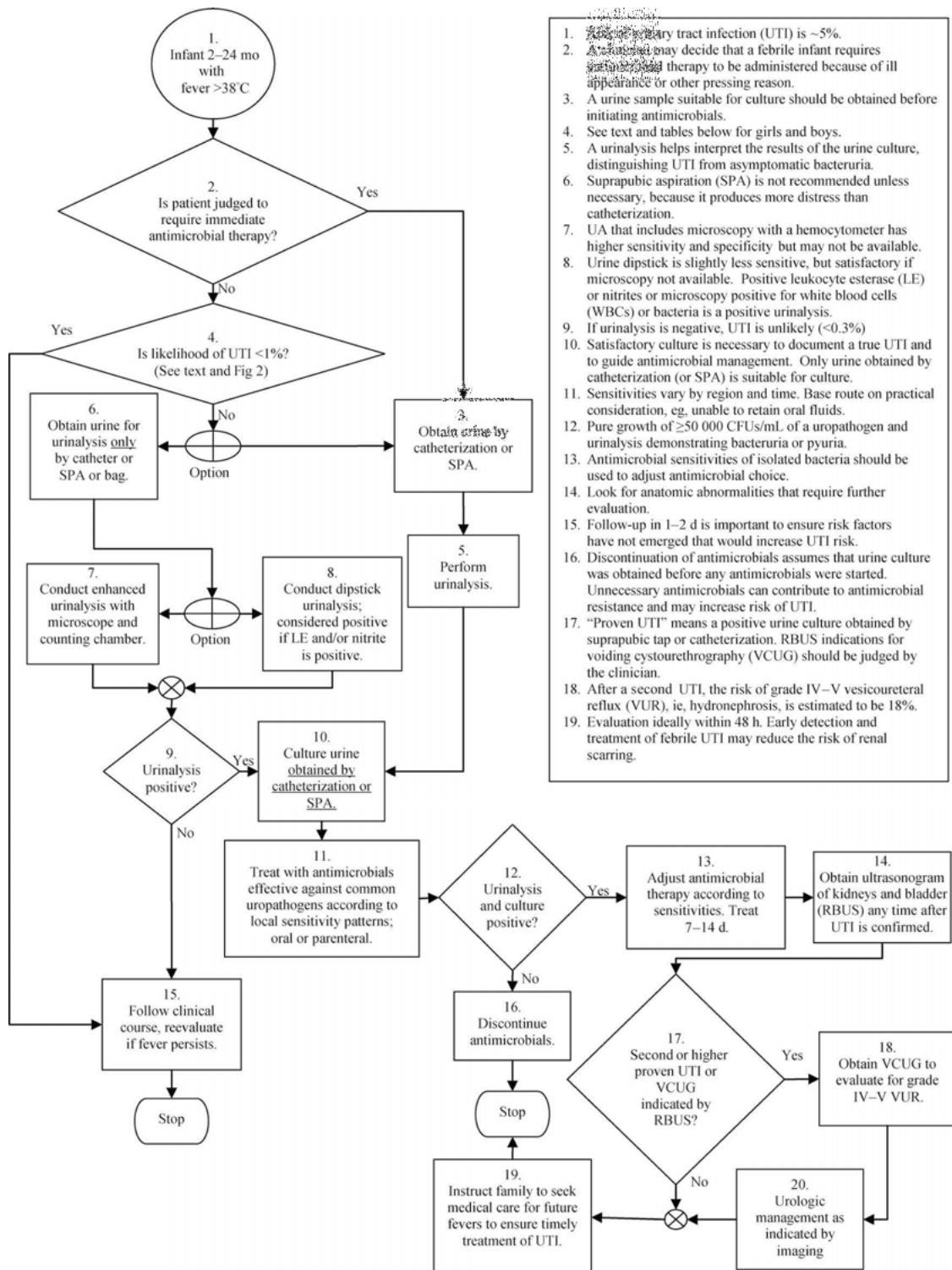
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1. Risk of urinary tract infection (UTI) is ~5%.
2. A clinician may decide that a febrile infant requires antimicrobial therapy to be administered because of ill appearance or other pressing reason.
3. A urine sample suitable for culture should be obtained before initiating antimicrobials.
4. See text and tables below for girls and boys.
5. A urinalysis helps interpret the results of the urine culture, distinguishing UTI from asymptomatic bacteriuria.
6. Suprapubic aspiration (SPA) is not recommended unless necessary, because it produces more distress than catheterization.
7. UA that includes microscopy with a hemocytometer has higher sensitivity and specificity but may not be available.
8. Urine dipstick is slightly less sensitive, but satisfactory if microscopy not available. Positive leukocyte esterase (LE) or nitrites or microscopy positive for white blood cells (WBCs) or bacteria is a positive urinalysis.
9. If urinalysis is negative, UTI is unlikely ($<0.3\%$).
10. Satisfactory culture is necessary to document a true UTI and to guide antimicrobial management. Only urine obtained by catheterization (or SPA) is suitable for culture.
11. Sensitivities vary by region and time. Base route on practical consideration, eg, unable to retain oral fluids.
12. Pure growth of $\geq 50\,000$ CFUs/mL of a uropathogen and urinalysis demonstrating bacteriuria or pyuria.
13. Antimicrobial sensitivities of isolated bacteria should be used to adjust antimicrobial choice.
14. Look for anatomic abnormalities that require further evaluation.
15. Follow-up in 1–2 d is important to ensure risk factors have not emerged that would increase UTI risk.
16. Discontinuation of antimicrobials assumes that urine culture was obtained before any antimicrobials were started. Unnecessary antimicrobials can contribute to antimicrobial resistance and may increase risk of UTI.
17. “Proven UTI” means a positive urine culture obtained by suprapubic tap or catheterization. RBUS indications for voiding cystourethrography (VCUG) should be judged by the clinician.
18. After a second UTI, the risk of grade IV–V vesicoureteral reflux (VUR), ie, hydronephrosis, is estimated to be 18%.
19. Evaluation ideally within 48 h. Early detection and treatment of febrile UTI may reduce the risk of renal scarring.

APPENDIX

Clinical practice guideline algorithm.

Technical Report—Diagnosis and Management of an Initial UTI in Febrile Infants and Young Children

S. Maria E. Finnell, MD, MS, Aaron E. Carroll, MD, MS, Stephen M. Downs, MD, MS, and the Subcommittee on Urinary Tract Infection

KEY WORDS

urinary tract infection, infants, children, vesicoureteral reflux, voiding cystourethrography, antimicrobial, prophylaxis, antibiotic prophylaxis, pyelonephritis

ABBREVIATIONS

UTI—urinary tract infection
VUR—vesicoureteral reflux
VCUG—voiding cystourethrography
CI—confidence interval
RR—risk ratio
RCT—randomized controlled trial
LR—likelihood ratio
SPA—suprapubic aspiration

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

abstract

FREE

OBJECTIVES: The diagnosis and management of urinary tract infections (UTIs) in young children are clinically challenging. This report was developed to inform the revised, evidence-based, clinical guideline regarding the diagnosis and management of initial UTIs in febrile infants and young children, 2 to 24 months of age, from the American Academy of Pediatrics Subcommittee on Urinary Tract Infection.

METHODS: The conceptual model presented in the 1999 technical report was updated after a comprehensive review of published literature. Studies with potentially new information or with evidence that reinforced the 1999 technical report were retained. Meta-analyses on the effectiveness of antimicrobial prophylaxis to prevent recurrent UTI were performed.

RESULTS: Review of recent literature revealed new evidence in the following areas. Certain clinical findings and new urinalysis methods can help clinicians identify febrile children at very low risk of UTI. Oral antimicrobial therapy is as effective as parenteral therapy in treating UTI. Data from published, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI when vesicoureteral reflux is found through voiding cystourethrography. Ultrasonography of the urinary tract after the first UTI has poor sensitivity. Early antimicrobial treatment may decrease the risk of renal damage from UTI.

CONCLUSIONS: Recent literature agrees with most of the evidence presented in the 1999 technical report, but meta-analyses of data from recent, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI. This finding argues against voiding cystourethrography after the first UTI. *Pediatrics* 2011;128:e749–e770

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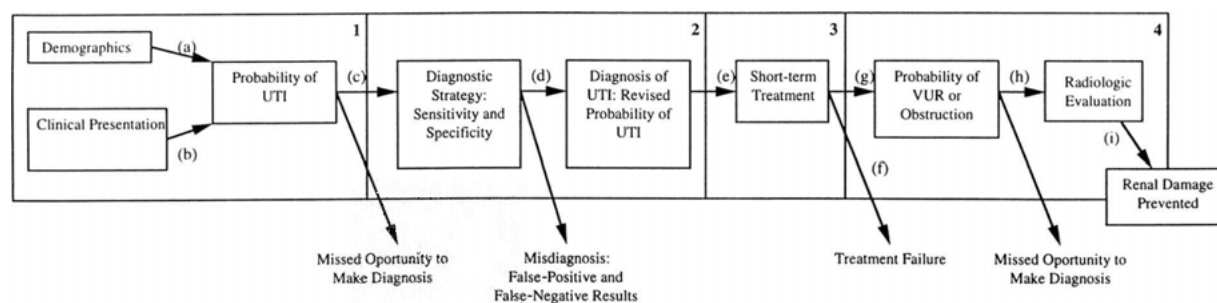


FIGURE 1

Evidence model from the 1999 technical report on the diagnosis and treatment of infants and children with UTIs.

In 1999, the Subcommittee on Urinary Tract Infection of the American Academy of Pediatrics released its guideline on detection, diagnosis, and management for children between 2 and 24 months of age with febrile urinary tract infections (UTIs).¹ The guideline was supported by a technical report² that included a critical review of the relevant literature and a cost-effectiveness analysis. Consistent with the policies of the American Academy of Pediatrics, the subcommittee has undertaken a revision of the guideline. This technical report was developed to support the guideline.³

The revised technical report was to be based on a selective review of the literature, focusing on changes in the evidence regarding detection, diagnosis, and management of UTIs in these children. The original technical report was designed around an evidence model (Fig 1). Each cell (numbered 1–4) corresponded to a stage in the recognition, diagnosis, or management of UTI. The boxes represented steps the clinician must follow, and the arrows represented the process of moving from one step to the next. Downward arrows represented undesirable consequences in management.⁴

In cell 1, the clinician must combine patient demographic data and other presenting clinical data to arrive at an assessment of the risk of UTI. Failure to do so results in a missed opportunity to make the diagnosis. In cell 2, the clinician must undertake a diagnostic

strategy, primarily involving laboratory testing, to arrive at a posterior (posttest) probability of UTI, ruling the diagnosis in or out. Poor test choices or interpretation of results can lead to misdiagnosis. In cell 3, the clinician must choose a treatment for acute UTI; in cell 4, the clinician must consider the possibility of structural or functional anomalies of the urinary tract and diagnose them appropriately to avoid ongoing renal damage.

Implicit in cell 4 is the idea that anomalies of the urinary tract, such as vesicoureteral reflux (VUR) and obstructions, may, if left untreated, lead to significant renal damage, resulting in hypertension or end-stage renal disease. Furthermore, it is assumed that treatment with medical or surgical therapies can prevent these consequences successfully.

The conclusions of the 1999 technical report were that there were high-quality data regarding the prevalence of UTI among febrile infants, the performance of standard diagnostic tests for UTI, and the prevalence of urinary tract abnormalities among children with UTI. The evidence indicating that certain patient characteristics (age, gender, and circumcision status) affected the probability of UTI was weaker. The evidence supporting the relationship between urinary tract abnormalities and future complications, such as hypertension or renal failure,

was considered very poor, and the effectiveness of treatments to prevent these complications was not addressed directly but was assumed.

The cost-effectiveness analysis using these data led to the conclusion that diagnosis and treatment of UTI and evaluation for urinary tract anomalies had borderline cost-effectiveness, costing approximately \$700 000 per case of hypertension or end-stage renal disease prevented. On the basis of these results, the subcommittee recommended testing all children between 2 and 24 months of age with fever with no obvious source for UTI, by culturing urine obtained through bladder tap or catheterization. As an option for children who were not going to receive immediate antimicrobial treatment, the committee recommended ruling out UTI through urinalysis of urine obtained with any convenient method. The committee concluded that children found to have a UTI should undergo renal ultrasonography and voiding cystourethrography (VCUG) for evaluation for urinary tract abnormalities, most frequently VUR.

Ten years later, the subcommittee has undertaken a review of the technical analysis for a revised guideline. The strategy for this technical report was to survey the medical literature published in the past 10 years for studies of UTIs in young children. The literature was examined for any data that varied significantly from those analyzed in the

first technical report. This survey found an emerging body of literature addressing the effectiveness of antimicrobial agents to prevent recurrent UTI. Therefore, the authors conducted a critical literature review and meta-analysis focused on that specific issue.

METHODS

Surveillance of Recent Literature

The authors searched Medline for articles published in the past 10 years with the medical subject headings “urinary tract infection” and “child (all).” The original search was conducted in 2007, but searches were repeated at intervals (approximately every 3 months) to identify new reports as the guideline was being developed. Titles were reviewed by 2 authors (Drs Downs and Carroll) to identify all articles that were potentially relevant and seemed to contain original data. All titles that were considered potentially relevant by either reviewer were retained. Abstracts of selected articles were reviewed, again to identify articles that were relevant to the guideline and that seemed to contain original data. Review articles that were relevant also were retained for review. Again, all abstracts that were considered potentially relevant by either reviewer were retained. In addition, members of the subcommittee submitted articles that they thought were relevant to be included in the review.

Selected articles were reviewed and summarized by 2 reviewers (Drs Finnell and Downs). The summaries were reviewed, and articles presenting potentially new information were retained. In addition, representative articles reinforcing evidence in the 1999 technical report were retained.

The most significant area of change in the UTI landscape was a new and growing body of evidence regarding the effectiveness of antimicrobial prophylaxis to prevent recurrent infections in

children with VUR. To explore this particular issue, a second, systematic, targeted literature search and formal meta-analysis were conducted to estimate the effectiveness of antimicrobial prophylaxis to prevent renal damage in children with VUR. In addition, 1 author (Dr Finnell) and the chairperson of the guideline committee (Dr Roberts) contacted the authors of those studies to obtain original data permitting subgroup analyses.

Targeted Literature Search and Meta-analysis

To examine specifically the effectiveness of antimicrobial prophylaxis to prevent recurrent UTI and pyelonephritis in children with VUR, a formal meta-analysis of randomized controlled trials (RCTs) was conducted. First, a systematic literature review focused on RCTs, including studies in press, was performed.

Inclusion Criteria

RCTs published in the past 15 years (1993–2009) that compared antimicrobial treatment versus no treatment or placebo treatment for the prevention of recurrent UTI and included a minimum of 6 months of follow-up monitoring were included. Published articles, articles in press, and published abstracts were included. There were no language restrictions. To be included, studies needed to enroll children who had undergone VCUG for determination of the presence and grade of VUR. Studies that examined antibiotic prophylaxis versus no treatment or placebo treatment were included.

Outcome Measures

The primary outcome was the number of episodes of pyelonephritis or febrile UTI diagnosed on the basis of the presence of fever and bacterial growth in urine cultures. A secondary outcome was an episode of any type of UTI, including cystitis, nonfebrile UTI, and

asymptomatic bacteriuria in addition to the cases of pyelonephritis or febrile UTI.

Search Methods

The initial literature search was conducted on June 24, 2008, and the search was repeated on April 14, 2009. Studies were obtained from the following databases: Medline (1993 to June 2008), Embase (1993 to June 2008), Cochrane Central Register for Controlled Trials, bibliographies of identified relevant articles and reviews, and the Web site www.ClinicalTrials.gov.

The search terms “vesico-ureteral reflux,” “VUR,” “vesicoureter*,” “vesico ureter*,” “vesicourethral,” or “vesico urethral” and “antibiotic,” “anti biotic,” “antibacterial,” “anti bacterial,” “antimicrobial,” “anti microbial,” “antiinfective,” or “anti infective” were used. The asterisk represents the truncation or wild card symbol, which indicates that all suffixes and variants were included. The search was limited to the publication types and subject headings for all clinical trials and included all keyword variants for “random” in Medline and Embase.⁵ In addition, the Web site www.ClinicalTrials.gov was searched on May 20, 2010.

The search strategy and the screening of the titles for selection of potentially relevant abstracts were completed by 1 reviewer (Dr Finnell). Two reviewers (Drs Finnell and Downs) screened selected abstracts to identify appropriate articles. Published articles and abstracts that met the inclusion criteria were included in the meta-analysis. Additional information was sought from authors whose articles or abstracts did not contain the information needed for a decision regarding inclusion. The selection process is summarized in Fig 2.

Assessment of Studies

The quality of selected articles and abstracts was assessed with the scoring

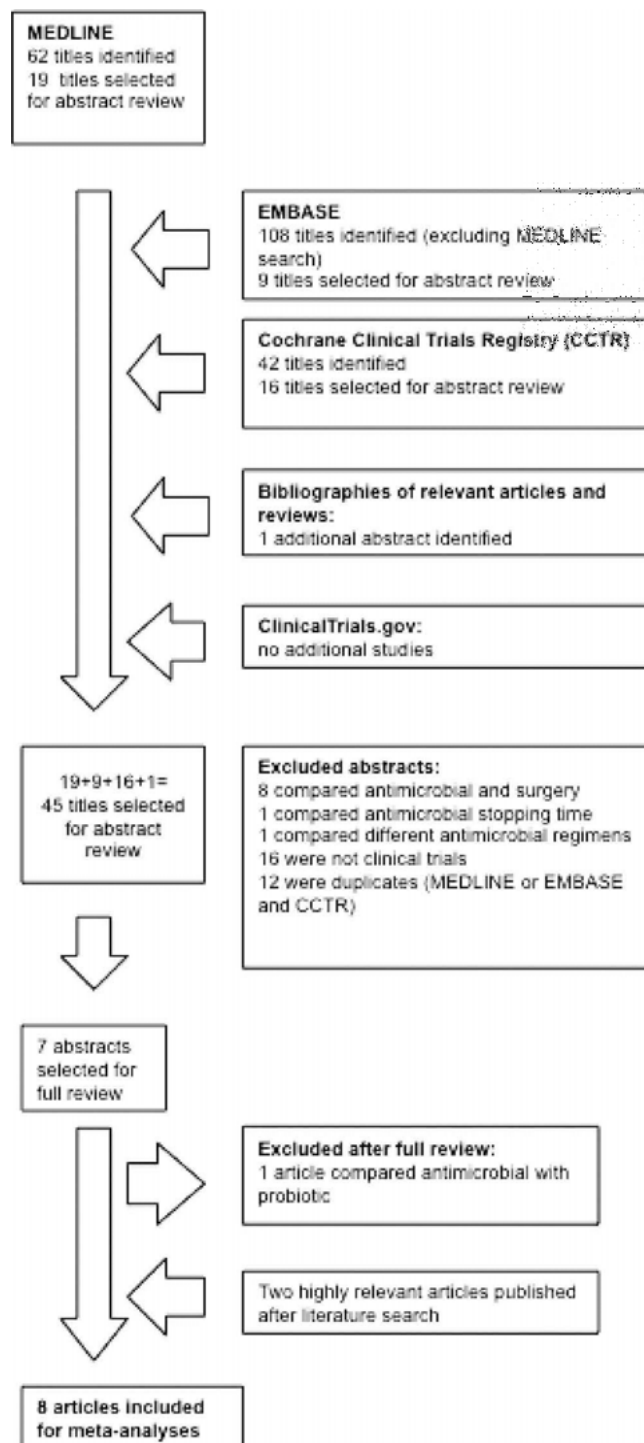


FIGURE 2
Study selection for meta-analyses.

system described by Downs and Black in 1998.⁶ Each study received scores (from 2 assessors) on a scale from 0 to 32. Six of the articles and abstracts were included in a first meta-analysis,

which evaluated febrile UTI or pyelonephritis as the outcome. A second meta-analysis, which included all studies with the outcome “all UTI,” also was conducted.

Meta-analyses

All statistical tests were performed by using Review Manager 5.1 (Nordic Cochrane Centre, Copenhagen, Denmark). The following settings were used for the analyses: dichotomous outcome and Mantel-Haenzel statistical method. Data were analyzed with a random-effects model. When no statistically significant effect and no statistical heterogeneity were detected, data also were analyzed with a fixed-effects model, because that type of analysis is more likely to detect a difference. The effect measure was presented as a risk ratio (RR). The results for the primary outcome (pyelonephritis or febrile UTI) and the secondary outcome (any type of UTI, including cystitis, non-febrile UTI, and asymptomatic bacteriuria) were calculated as point estimates with corresponding 95% confidence intervals (CIs). Heterogeneity was analyzed by using the Q statistic with a threshold of $P < .05$. The number of studies was insufficient for assessment of publication bias with a funnel plot.

Meta-analyses of Data According to VUR Grade and for Children 2 to 24 Months of Age

The published data on which the meta-analyses were based did not contain subgroup data relevant to the practice guideline. Specifically, some studies did not report outcomes according to the severity of VUR, and some did not report outcomes specific to the age range of interest (2–24 months). Therefore, the committee chairperson contacted the authors of the reports included in the meta-analysis, to obtain original data. Data on recurrence according to VUR grade and for the subgroup of children 2 to 24 months of age were received from the authors, and these data were analyzed in separate meta-analyses.

RESULTS

Surveillance of Recent Literature

The surveillance of recent literature yielded 1308 titles. Of those, 297 abstracts were selected for review. From among the abstracts, 159 articles were selected for full review. The results of this surveillance, as well as the full review and meta-analyses, are organized according to the evidence diagram in Fig 1.

Box 1: Prevalence and Risk Factors for UTI

The Presence of UTI Should Be Considered for Any Child 2 Months to 2 Years of Age With Unexplained Fever

The previous technical report described a very consistent UTI prevalence of 5% among children 2 to 24 months of age with a fever without obvious source. In 1996, Hoberman et al⁷ conducted a study of urine diagnostic tests with a cohort of 4253 infants with fever and found a prevalence of 5%. Similarly, in a 1999 cohort study of 534 children 3 to 36 months of age with a temperature of more than 39°C and no apparent source of fever, UTI prevalence was determined to be 5%.⁸ In a 1998 cohort study of 2411 children (boys and girls <12 months of age and girls 12–24 months of age) seen in the emergency department with a temperature of more than 38.5°C, Shaw et al⁹ determined the prevalence of UTI to be 3.3%. Because 84% of those children were black, this estimate may be low for the general population (see below). In a meta-analysis of 14 studies, the pooled prevalence of UTI was 7% (95% CI: 5.5%–8.4%) among febrile children 0 to 24 months of age, of both genders, with or without additional symptoms of UTI.¹⁰ In the 6- to 12-month age group, however, the prevalence was 5.4%; in the 12- to 24-month age group, the prevalence was 4.5%. Taken to-

TABLE 1 LRs and Posttest Probabilities of UTI for Infant Boys According to Number of Findings Present

Finding	LR		Posttest Probability, %					
			All Boys		Circumcised Boys		Uncircumcised Boys	
	Positive	Negative	After Positive Results	After Negative Results	After Positive Results	After Negative Results	After Positive Results	After Negative Results
Uncircumcised	2.8	0.33	5.9	0.7	—	—	—	—
History of UTI	2.6	0.96	5.5	2.1	1.8	0.7	14.0	5.7
Temperature of >39°C	1.4	0.76	3.1	1.7	1.0	0.5	8.1	4.5
Fever without apparent source	1.4	0.69	3.1	1.5	1.0	0.5	8.1	4.1
Ill appearance	1.9	0.68	4.1	1.5	1.3	0.5	10.6	4.1
Fever for >24 h	2.0	0.9	4.3	2.0	1.4	0.6	11.1	5.3
Nonblack race	1.4	0.52	3.1	1.2	1.0	0.4	8.1	3.2

gether, these estimates are consistent with a pooled prevalence of 5% determined in earlier studies.

The previous technical report examined the effects of age, gender, and circumcision status on the prevalence of UTI. The conclusion was that boys more than 1 year of age who had been circumcised were at sufficiently low risk of UTI (<1%) that evaluation of this subpopulation would not be cost-effective. New work confirms an approximately threefold to fourfold decreased risk of UTI among circumcised boys.¹⁰ The difference seems to be greater for younger children.¹¹ Additional clinical characteristics were shown more recently to affect the risk of UTI among febrile infants and children. From a study by Shaikh et al,¹² a set of likelihood ratios (LRs) for various risk factors for UTI was derived (Table 1).

A simplified way to examine the data on boys from Shaikh et al¹² is first to ex-

clude boys with a history of UTI, because the guideline addresses only first-time UTIs, and to exclude those with ill appearance, because they are likely to require antimicrobial agents, in which case a urine specimen would be required. Finally, boys with and without circumcision should be considered separately. This leaves 4 risk factors for boys who present with fever, namely, temperature above 39°C, fever for more than 24 hours, no apparent fever source, and nonblack race. All 4 have similar LRs. If 2 assumptions are made, then the decision rule can be simplified. The first assumption is that, as a first approximation, each risk factor has a positive LR of 1.4 and a negative LR of 0.7. The second assumption is that the presence of each risk factor is conditionally independent of the others, given the presence or absence of UTI. With these reasonable assumptions, Table 2 applies to boys with no previous history of UTI

TABLE 2 LRs and Posttest Probabilities of UTI for Febrile Infant Boys According to Number of Findings Present

No. of Risk Factors	LR	Posttest Probability, %		
		All Boys	Uncircumcised	Circumcised
0	0.34	0.8	2.1	0.2
1	0.69	1.5	4.1	0.5
2	1.37	3.0	7.9	1.0
3	2.74	5.8	14.7	1.9
4	5.49	11.0	25.6	3.7

Risk factors: temperature above 39°C, fever for more than 24 hours, no apparent fever source, and nonblack race.

TABLE 3 LRs and Posttest Probabilities of UTI for Febrile Infant Girls According to Number of Findings Present (Prospective Original Study)

Cutoff Value, No. of Factors	LR		Posttest Probability, %	
	Positive	Negative (Approximate)	Below Cutoff Value	At or Above Cutoff Value
1	1.04	0.20	0.8	5.1
2	1.35	0.17	0.8	6.5
3	2.5	0.42	2.1	11.4
4	9.4	0.79	3.9	33.0
5	15.8	0.95	4.7	45.0

Risk factors: less than 12 months of age, white race, temperature > 39°C, fever for at least 2 days, and absence of another source of infection.

and do not appear ill. The LR is calculated as $LR = (1.4)^p \times (0.7)^n$, where p is the number of positive findings and n is the number of negative findings. This assumes that the clinician has assessed all 4 risk factors. It should be noted that, for uncircumcised boys, the risk of UTI never decreases below 2%. For circumcised boys, the probability exceeds 1% if there are 2 or more risk factors.

Other studies have shown that the presence of another, clinically obvious source of infection,¹³ particularly documented viral infections,¹⁴ such as respiratory syncytial virus infections,¹⁵ reduces the risk of UTI by one-half. In a series of studies conducted by Gorelick, Shaw, and others,^{9,16,17} male gender, black race, and no history of UTI were all found to reduce the risk. The authors derived a prediction rule specifically for girls, with 95% sensitivity and 31% specificity. In a subsequent validation study, they confirmed that these findings had predictive power, but the validation study used a weaker, retrospective, case-control design, compared with the more-robust, prospective, cohort design of the original derivation study. On the basis of the earlier cohort study and starting with a baseline risk of 5%, a child scoring low on the prediction rule would have a slightly less than 1% risk of UTI. To score this low on the prediction rule, a young girl would have to exhibit no more than 1 of the following features: less than 12 months of

age, white race, temperature of more than 39°C, fever for at least 2 days, or absence of another source of infection.

However, those authors evaluated their decision rule with several different cutoff points, to determine the score below which the risk of UTI decreased below a test threshold of 1%. Unfortunately, the published article did not include the set of negative LRs needed to reproduce the posterior probabilities.¹⁷ However, it was possible to approximate them through extrapolation from the receiver operating characteristic curve presented. On the basis of these estimated negative LRs and the positive LRs provided in the article,¹⁷ Table 3 was derived. For each cutoff value in the number of risk factors, Table 3 shows the posterior probability for children with fewer than that number of risk factors (below the cutoff value) and for those with that number of risk factors *or more*. Therefore, the posttest probability is not the risk of UTI for children with exactly that

TABLE 4 LRs and Posttest Probabilities of UTI for Febrile Infant Girls According to Number of Findings Present (Retrospective Validation Study)

No. of Findings	LR	Posttest Probability, %
0 or 1	1.02	0.8
2	1.10	0.9
3	1.26	1.0
4	3.04	2.4
5	2.13	1.7

Risk factors: less than 12 months of age, white race, temperature > 39°C, fever for at least 2 days, and absence of another source of infection.

number of risk factors. Similar results could be derived from the validation study and are shown in Table 4. However, because the second study had a weaker design, the values in Table 3 are more reliable.

These studies provide criteria for practical decision rules that clinicians can use to select patients who need urine samples for analysis and/or culture. They do not establish a threshold or maximal risk of UTI above which a urine sample is needed. However, in surveys of pediatricians, Roberts et al¹⁸ found that only 10% of clinicians thought that a urine culture is indicated if the probability of UTI is less than 1%. In addition, the cost-effectiveness analysis published in the 1999 technical report set a threshold of 1%. However, circumstances such as risk of loss to follow-up monitoring or other clinician concerns may shift this threshold up or down.

TABLE 5 List of Test Characteristics of Diagnostic Tests for UTI Reported in 1999 Technical Report²

Test	Sensitivity, %			Specificity, %		
	Range	Median	Mean	Range	Median	Mean
Leukocyte esterase test	67–94	84	83	64–92	77	78
Nitrite test	15–82	58	53	90–100	99	98
Blood assessment	25–64	53	47	60–89	85	78
Protein assessment	40–55	53	50	67–84	77	76
Microscopy, leukocytes	32–100	78	73	45–98	87	81
Microscopy, bacteria	16–99	88	81	11–100	93	83
Leukocyte esterase or nitrite test	90–100	92	93	58–91	70	72
Any positive test results in urinalysis	99–100	100	99.8	60–92	63	70

TABLE 6 Test Characteristics of Laboratory Tests for UTI in Children

Study	Test	Population	n	Sensitivity, %	Specificity, %
Lockhart et al ¹⁹ (1995)	Leukocyte esterase or nitrite test results positive	Prospective sample, <6 mo of age, ED	207	67	79
Hoberman et al ⁷ (1996)	Any bacteria with Gram-staining >10 white blood cells per counting chamber or any bacteria per 10 oil emersion fields	<2 y of age, 95% febrile, ED	4253	96	93
Shaw et al ⁹ (1998)	Enhanced urinalysis Dipslide or standard urinalysis	Infants <12 mo of age and girls <2 y of age, $\geq 38.5^{\circ}\text{C}$, ED	3873	94 83	84 87
Lin et al ²⁰ (2000)	Hemocytometer, ≥ 10 cells per μL	Systematic review, febrile infants hospitalized, febrile UTI	NA	83	89

ED indicates emergency department; NA, not applicable.

Box 2: Diagnostic Tests for UTI

The 1999 technical report reviewed a large number of studies that described diagnostic tests for UTI. The results are summarized in Table 5. This updated review of the literature largely reinforced the findings of the original technical report.

More-recent work compared microscopy, including the use of hemocytometers and counting chambers (enhanced urinalysis), with routine urinalysis or dipslide reagents (Table 6). Lockhart et al¹⁹ found that the observation of any visible bacteria in an uncentrifuged, Gram-stained, urine sample had better sensitivity and specificity than did combined dipslide leukocyte esterase and nitrite test results. Hoberman et al⁷ in 1996 and Shaw et al²⁰ in 1998 both evaluated enhanced urinalysis, consisting of more than 10 white blood cells in a counting chamber or any bacteria seen in 10 oil emersion fields; they found sensitivity of 94% to 96% and specificity of 84% to 93%. In 2000, Lin et al²¹ found that a count of at least 10 white blood cells per μL in a hemocytometer was less sensitive (83%) but quite specific (89%). Given the sensitivity of enhanced urinalysis, the probability of UTI for a typical febrile infant with a previous likelihood of UTI of 5% would be reduced to 0.2% to 0.4% with negative enhanced urinalysis results.

Obtaining a Urine Sample

In the UTI practice parameters from 1999, the subcommittee defined the gold standard of a UTI to be growth of bacteria on a culture of urine obtained through suprapubic aspiration (SPA). In the previous technical report, SPA was reported to have success rates ranging from 23% to 90%,^{22–24} although higher success rates have been achieved when SPA is conducted under ultrasonographic guidance.^{25,26} SPA is considered more invasive than catheterization and, in RCTs from 2006²⁷ and 2010,²⁸ pain scores associated with SPA were significantly higher than those associated with catheterization. This result was found for both boys and girls. Similar to previous studies, these RCTs also revealed lower success rates for SPA (66% and 60%), compared with catheterization (83% and 78%).^{27,28} In comparison with SPA results, cultures of urine specimens obtained through catheterization are 95% sensitive and 99% specific.^{7,11,12}

Cultures of bag specimens are difficult to interpret. In the original technical report, sensitivity was assumed to be 100% but the specificity of bag cultures was shown to range between 14% and 84%.² Our updated surveillance of the literature did not show that these numbers have improved.^{29–33} One article suggested that a new type of collection bag may result in improved specificity,³⁴ but that study was not controlled. With a prevalence of 5% and specificity of 70%,

the positive predictive value of a positive culture result for urine obtained in a bag would be 15%. This means that, of all positive culture results for urine obtained in a bag, 85% would be false-positive results.

Box 3: Short-term Treatment of UTIs

General Principles of Treatment

Published evidence regarding the short-term treatment of UTIs supports 4 main points. First, complications, such as bacteremia or renal scarring, are sufficiently common to necessitate early, thorough treatment of febrile UTIs in infants.³⁵ Second, treatment with orally administered antimicrobial agents is as effective as parenteral therapy.^{36,37} Third, bacterial sensitivity to antimicrobial agents is highly variable across time and geographic areas, which suggests that therapy should be guided initially by local sensitivity patterns and should be adjusted on the basis of sensitivities of isolated pathogens.^{38,39} Fourth, meta-analyses have suggested that shorter durations of oral therapy may not have a disadvantage over longer courses for UTIs. However, those studies largely excluded febrile UTI and pyelonephritis.⁴⁰

Experimental and Clinical Data

Support the Concept That Delays in the Institution of Appropriate Treatment for Pyelonephritis Increase the Risk of Renal Damage

The 1999 technical report cited evidence that febrile UTIs in children less

TABLE 7 Recent Studies Documenting the Prevalence of VUR Among Children With UTI

Study	Description	n	Prevalence, %
Sargent and Stringer ⁵⁰ (1995)	Retrospective study of first VCUG for UTI in children 1 wk to 15 y of age	309	30
Craig et al ⁵¹ (1997)	Cross-sectional study of children <5 y of age with first UTI	272	28
McDonald et al ⁵² (2000)	Retrospective chart review of children with VCUG after UTI	176	19
Oostenbrink et al ⁵³ (2000)	Cross-sectional study of children <5 y of age with first UTI	140	26
Mahant et al ⁵⁴ (2001)	Retrospective chart review of children with VCUG after UTI	162	22
Mahant et al ⁵⁵ (2002)	Retrospective review of VCUG in children <5 y of age admitted with first UTI	162	22
Chand et al ⁵⁶ (2003)	Retrospective review of VCUG or radionuclide cystogram in children <7 y of age	15 504	35
Fernandez-Menendez et al ⁴⁴ (2003)	Prospective cohort study of 158 children <5 y of age (85% < 2 y) with first UTI	158	22
Camacho et al ⁴¹ (2004)	Prospective cohort study of children 1 mo to 12 y of age (mean age: 20 mo) with first febrile UTI	152	21
Hansson et al ⁵⁷ (2004)	Retrospective cross-sectional study of children <2 y of age with first UTI	303	26
Pinto ⁵⁸ (2004)	Retrospective chart review of first VCUG for UTI in children 1 mo to 14 y of age	341	30
Zamir et al ⁵⁹ (2004)	Cohort study of children 0–5 y of age hospitalized with first UTI	255	18

than 2 years of age are associated with bacterial sepsis in 10% of cases.³⁵ Furthermore, renal scarring is common among children who have febrile UTIs. The risk is higher among those with higher grades of VUR⁴¹ but occurs with all grades, even when there is no VUR. Although it was not confirmed in all studies,^{42,43} older work² and newer studies⁴⁴ demonstrated an increased risk of scarring with delayed treatment. Children whose treatment is delayed more than 48 hours after onset of fever may have a more than 50% higher risk of acquiring a renal scar.

Oral Versus Intravenous Therapy

In a RCT from 1999, Hoberman et al³⁶ studied children 1 to 24 months of age with febrile UTIs. They compared 14 days of oral cefixime treatment with 3 days of intravenous cefotaxime treatment followed by oral cefixime treatment to complete a 14-day course. The investigators found no difference in outcomes between children who were treated with an orally administered, third-generation cephalosporin alone and those who received intravenous treatment.

In a Cochrane review, Hodson et al³⁷ evaluated studies with children 0 to 18 years of age, examining oral versus intravenous therapy. No significant differences were found in duration of fever (2 studies; mean difference: 2.05 hours [95% CI: -0.84 to 4.94 hours]) or

renal parenchymal damage at 6 to 12 months (3 studies; RR: 0.80 [95% CI: 0.50–1.26]) between oral antimicrobial therapy (10–14 days) and intravenous antimicrobial treatment (3 days) followed by oral antimicrobial treatment (11 days).

Duration of Therapy

In the 1999 technical report, data slightly favoring longer-duration (7–10 days) over shorter-duration (1 dose to 3 days) antimicrobial therapy for pediatric patients with UTIs were presented.² Since then, several meta-analyses with different conclusions have been published on this topic.^{40,45,46} A 2003 Cochrane review addressing the question analyzed studies that examined the difference in rates of recurrence for positive urine cultures after treatment.⁴⁰ It compared short (2–4 days) and standard (7–14 days) duration of treatment for UTIs and found no significant difference in the frequency of bacteriuria after completion of treatment (8 studies; RR: 1.06 [95% CI: 0.64–1.76]). Although the authors of the review did not exclude studies of children with febrile UTIs or pyelonephritis, each individual study included in the meta-analysis had already excluded such children. To date, there are no conclusive data on the duration of therapy for children with febrile UTIs or pyelonephritis.

Proof of Cure

Data supporting routine repeat cultures of urine during or after completion of antimicrobial therapy were not available for the 1999 technical report. Retrospective studies did not show “proof of bacteriologic cure” cultures to be beneficial.^{47,48} Studies demonstrating that clinical response alone ensures bacteriologic cure are not available.

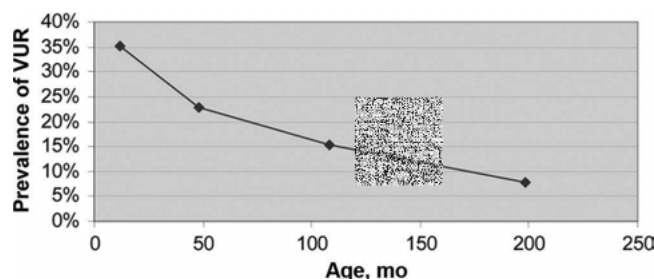
Box 4: Evaluation and Management of Urinary Tract Abnormalities

Prevalence of VUR

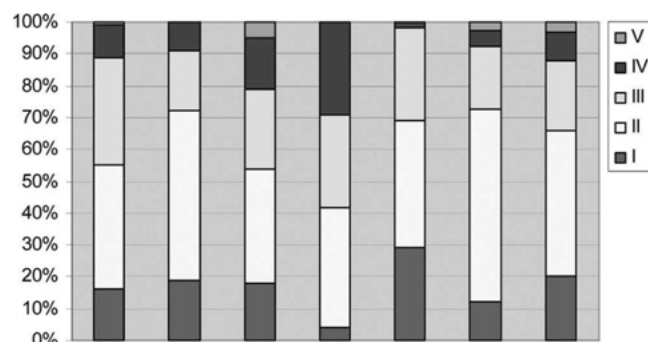
Several cohort studies published since the 1999 technical report provide estimates of the prevalence of VUR of various grades among infants and children with UTIs (Table 7). Overall, these estimates are reasonably consistent with those reported in earlier studies, although the grades of reflux are now reported more consistently, by using the international system of radiographic grading of VUR.⁴⁹

The prevalence of VUR among children in these studies varies between 18% and 35%. The weighted average prevalence is 34%, but this is largely driven by the enormous retrospective study by Chand et al.⁵⁶ Most studies report a rate of 24% or less, which is less than the estimate of VUR prevalence in the 1999 technical report.

Data on the prevalence of VUR among children *without* a history of UTI do not

**FIGURE 3**

Prevalence of VUR as a function of the midpoint of each age stratum, as reported by Chand et al.⁵⁶

**FIGURE 4**

Distribution of reflux grades among children with VUR.^{41,44,51,56,57,62,63}

exist. Using a retrospective approach and existing urine culture data, Hanula and Ventola and colleagues,^{60,61} in 2 separate publications, found similar rates of prevalence of any grade of VUR among children with proven (37.4%) or certain (36%) UTI versus false (34.8%) or improbable (36%) UTI. These results suggest that VUR is prevalent even among children without a history of UTI.

The prevalence of VUR decreases with age. This was approximated by analysis across studies in the 1999 technical report. Since then, Chand et al⁵⁶ reported the prevalence VUR within age substrata of their cohort. Figure 3 shows the prevalence of VUR plotted as a function of the midpoint of each age stratum.

Seven studies reported the prevalence of different grades of reflux, by using the international grading system.^{41,44,51,56,57,62,63} The distributions of different reflux grades among children who had VUR are shown in Fig 4. There is significant variability in the relative

predominance of each reflux grade, but grades II and III consistently are the most common. With the exception of the study by Camacho et al,⁴¹ all studies showed grades IV and V to be the least frequent, and grade V accounted for 0% to 5% (weighted average: 3%) of reflux. With that value multiplied by the prevalence of VUR among young children with a first UTI, we

would expect grade V reflux to be present in <1% of children with a first UTI.

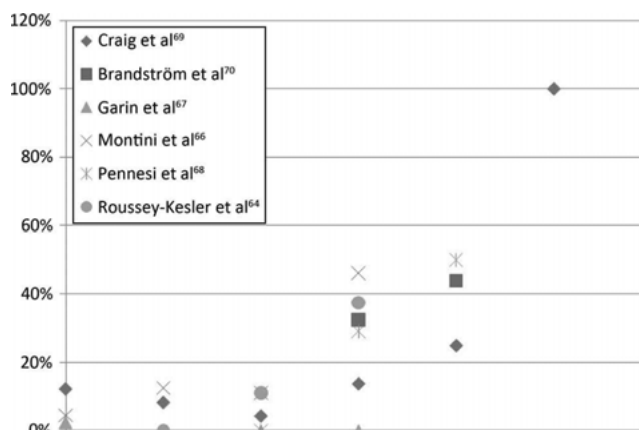
It has been suggested that the risk of VUR and, more specifically, high-grade VUR may be higher for children with recurrent UTI than for children with a first UTI. Although it was not tested directly in the studies reviewed, this idea can be tested and the magnitude of the effect can be estimated from the data found in the literature search for this meta-analysis.^{64–70} These data clearly demonstrate that the risk of UTI recurrence is associated with VUR (Fig 5). Furthermore, this relationship allows the likelihood of each grade of reflux (given that a UTI recurrence has occurred) to be estimated by using Bayes' theorem, as follows:

$$p(\text{VUR}_i|\text{UTI})$$

$$= \frac{p(\text{UTI}|\text{VUR}_i) \times p(\text{VUR}_i)}{\sum_{i=0}^V p(\text{UTI}|\text{VUR}_i) \times p(\text{VUR}_i)},$$

where $p(\text{UTI}|\text{VUR}_i)$ refers to the probability of VUR of grade i given the recurrence of UTI. If it is assumed that the conditional probabilities remain the same with second or third UTIs, then Bayes' theorem can be reapplied for a third UTI as well.

By using estimates of $p(\text{UTI}|\text{VUR})$ (Fig 5) and the previously determined distri-

**FIGURE 5**

Probability of a recurrent febrile UTI as a function of VUR grade among infants 2 to 24 months of age in the control groups of the studies included in meta-analyses.^{64,66–70}

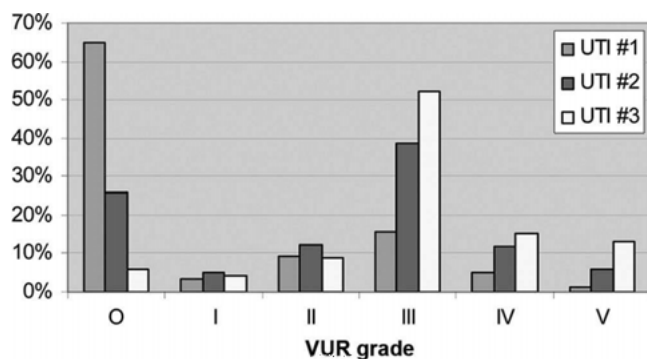


FIGURE 6

Distribution of VUR grades after different numbers of UTIs.

butions of VUR grades (Fig 4), a very approximate estimate of the distribution of VUR grades after the first, second, and third UTI can be made (Fig 6). The likelihood that there is no VUR decreases rapidly. Conversely, the likelihood of VUR grades III to V increases rapidly. The risk of grades I and II changes little.

Ultrasonography

Ultrasonography is used as a noninvasive technique to identify renal abnormalities in children after UTI. The sensitivity of the test varies greatly and has been reported to be as low as 5% for detection of renal scarring^{71–73} and 10% for detection of VUR.⁷⁴ However, most studies report moderate specificity.

One possible reason for a decrease in specificity is that, in animal models, *Escherichia coli* endotoxin has been shown to produce temporary dilation of the urinary tract during acute infection.⁷⁵ Therefore, use of routine ultrasonography for children with UTIs during acute infection may increase the false-positive rate. However, no human data are available to confirm this hypothesis.

Ultrasonography is used during acute infection to identify renal or perirenal abscesses or pyonephrosis in children who fail to experience clinical improvement despite antimicrobial therapy. The sensitivity of ultrasonography for such complications is thought to be

very high, approaching 100%.⁷⁶ Therefore, ultrasonography in the case of a child with a UTI who is not responding to therapy as expected can be very helpful in ruling out these infectious complications.

Ultrasonography also is advocated for screening for renal abnormalities such as hydronephrosis, suggesting posterior urethral valves, ureteropelvic junction obstruction, or ureteroceles. The evidence model illustrates the expected outcomes from routine ultrasonography of the kidneys, ureters, and bladder after the first febrile UTI in infants and young children (Fig 7). The model is based on the study results documented in Tables 8 and 9 and a strategy of performing kidney and bladder ultrasonography for all infants with UTIs. The numbers are not exact for 2 reasons, namely, (1) study populations vary and do not always precisely meet the definitions of 2 to 24 months of age and febrile without an-

other fever source and, (2) even within similar populations, reported rates vary widely.

Ultrasonography yields ~15% positive results. However, it has a ~70% false-negative rate for reflux, scarring, and other abnormalities. Limited data exist regarding the false-negative rate for high-grade VUR (grade IV and V), but the studies reviewed presented 0% to 40% false-negative rates for detection of grade IV reflux through ultrasonography.^{59,74} Among the 15% of results that are positive, between 1% and 24% are false-positive results. Of the true-positive results, ~40% represent some dilation of the collecting system, such as would be found on a VCUG; 10% represent abnormalities that are potentially surgically correctable (eg, ureteroceles or ureteropelvic junction obstruction). Approximately one-half represent findings such as horseshoe kidneys or renal scarring, for which there is no intervention but which might lead to further evaluations, such as technetium-99m–labeled dimercaptosuccinic acid renal scintigraphy. The 40% with dilation of the collecting system are problematic. This represents only a small fraction of children ($15\% \times 88\% \times 40\% = 5\%$) with first UTIs who would be expected to have VUR before ultrasonography. Ultrasonography does not seem to be enriching for this population (although ultrasonography might identify a population with higher-grade VUR).

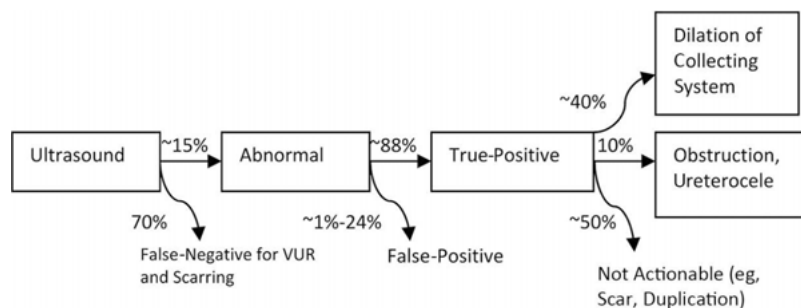


FIGURE 7

Evidence model for ultrasonography after a first UTI.

TABLE 8 Summary of Ultrasonography Literature

Study	n/N (%)	Comments
False-negative rate		
Scarring		
Smellie et al ⁷³ (1995)	7/20 (35)	Reported as renal units
Barry et al ⁷⁷ (1998)	23/170 (14)	
Moorthy et al ⁷¹ (2004)	219/231 (95)	
Sinha et al ⁷⁸ (2007)	61/79 (77)	
Montini et al ⁷⁹ (2009)	33/45 (73)	
VUR		
Smellie et al ⁷³ (1995)	21/36 (58)	
Mahant et al ⁵⁵ (2002)	14/35 (40)	
Hoberman et al ⁷⁴ (2003)	104/117 (90)	
Zamir et al ⁵⁹ (2004)	38/47 (81)	
Montini et al ⁷⁹ (2009)	48/66 (73)	
Other		
Smellie et al ⁷⁴ (1995)	5/5 (100)	Duplex kidney
False-positive rate		
Scarring		
Barry et al ⁷⁷ (1998)	11/478 (2)	
Moorthy et al ⁷¹ (2004)	12/699 (1.7)	
Sinha et al ⁷⁸ (2007)	9/870 (1)	
Monitini et al ⁷⁹ (2009)	26/255 (10)	
VUR		
Smellie et al ⁷³ (1995)	2/12 (17)	Normal VCUG, DMSA, and IVU results
Mahant et al ⁵⁵ (2002)	30/127 (24)	
Hoberman et al ⁷⁴ (2003)	17/185 (10)	
Zamir et al ⁵⁹ (2004)	27/208 (13)	
Other		
Giorgi et al ⁸⁰ (2005)	21/203 (10)	

IVU indicates intravenous urography; DMSA, dimercaptosuccinic acid.

Prenatal Ultrasonography

Urinary tract abnormalities also may be identified during prenatal ultrasonography,^{85–87} which theoretically would decrease the number of new abnormalities found through later ultrasonography.⁸¹ However, the extent to which normal prenatal ultrasonographic findings decrease the need for later studies remains in doubt.

Miron et al⁸⁸ studied 209 children who underwent ultrasonography prenatally and again after a UTI. They found that, among 9 children with abnormal ultrasonographic results after UTI, 7 had normal prenatal ultrasonographic results. These cases included 3 cases of hydronephrosis, 3 cases of moderate dilation, and 1 case of double collecting system. Similarly, in a study by Lakhoo et al⁸⁹ in 1996, 22 of 39 children with UTIs had normal prenatal ultrasonographic results but “abnormal” post-UTI ultrasonographic results; the abnormalities

were not described. These studies suggest that normal prenatal ultrasonographic findings may not be sufficient to obviate the need for additional studies if a UTI occurs in infancy.

Results of Targeted Literature Review and Meta-analysis on Prophylaxis to Prevent Recurrent UTI

Study Identification

For the meta-analysis of studies on the effectiveness of antimicrobial agents to prevent recurrent UTI in children with VUR, we reviewed a total of 213 titles from our primary literature search. Of those, 45 were retained for abstract review on the basis of the title, of which 7 were selected for full review. Six of the studies met the inclusion criteria. Figure 2 summarizes the selection process.

Thirty-eight abstracts were excluded before full review (Fig 2). Eight of those

studies were RCTs comparing prophylactic antimicrobial agent use with some type of surgical intervention. None of those studies included a placebo arm.^{90–97} One study compared different lengths of antimicrobial prophylaxis.⁹⁸ Another study compared different antimicrobial regimens but did not include a placebo arm.⁹⁹ Sixteen studies were determined, on closer inspection, to be not clinical trials but prospective cohort studies, reviews, systematic reviews, or meta-analyses. Twelve studies were found twice, either in Medline or Embase and the Cochrane Clinical Trials Registry.

One article was excluded after full review (Fig 2). That study compared prophylactic antimicrobial agent use with probiotic use.⁶⁵ The study was not included in the meta-analysis, but the results are described separately.

There are RCTs of antimicrobial prophylaxis that are older than 15 years. In 4 studies from the 1970s, a total of 179 children were enrolled.^{100–103} Less than 20% of those children had VUR. Because of limited reporting of results in that subgroup, those older studies were not included in the analyses.

Two additional RCTs comparing antimicrobial prophylaxis and placebo treatment for children were published in October 2009.^{69,70} The first trial enrolled children 0 to 18 years of age after a first UTI, with 2% of enrolled children (12 of 576 children) being more than 10 years of age. The second trial enrolled children diagnosed as having VUR after a first UTI (194 [96%] of 203 children) or after prenatal ultrasonography (9 [4%] of 203 children), who were then assigned randomly to receive antimicrobial prophylaxis, surveillance, or endoscopic therapy, at 1 to 2 years of age. The majority of these children (132 children [65%]) had been diagnosed as having VUR before 1

TABLE 9 Distribution of Positive Ultrasonographic Findings

Study	n/N (%)
Alon and Ganapathy ⁶² (1999)	19/124 (15)
Minimal unilateral changes	
VUR	2 (1.6)
Normal VCUG findings	2 (1.6)
Resolved on repeat study	2 (1.6)
Not monitored further	3 (2.4)
Major changes	8 (6.5)
VUR	1 (1.6)
Normal findings	1 (1.6)
Posterior urethral valve	1 (1.6)
Hydronephrosis	1 (1.6)
Gelfand et al ⁶¹ (2000)	141/844 (16.7)
Bladder wall thickening	31 (3.7)
Hydronephrosis	6 (0.7)
Parenchymal abnormalities	42 (5.0)
Pelvic dilatation	27 (3.2)
Renal calculus	1 (0.1)
Simple renal cyst	1 (0.1)
Urethelial thickening	31 (3.7)
Jothilakshmi et al ⁶² (2001)	42/262 (16)
Duplex kidney	3 (1)
Crossed renal ectopia	1 (0.38)
Horseshoe kidney	1 (0.38)
Hydronephrosis	5 (1.9)
Megaureter	6 (2.3)
Polycystic kidney	1 (0.38)
Pelviureteric junction obstruction	1 (0.38)
Posterior urethral valve	2 (0.76)
Renal calculus	3 (0.01)
Rotated kidney	2 (0.76)
Ureterocele	2 (0.76)
VUR	7 (2.7)
Hoberman et al ⁷⁴ (2003)	37/309 (12)
Dilated pelvis	13 (4.2)
Pelvic dilatation	12 (3.9)
Hydronephrosis	2 (0.6)
Dilated ureter	9 (2.9)
Double collecting system	3 (1.0)
Extrarenal pelvis	1 (0.3)
Calculus	1 (0.3)
Zamir et al ⁵⁹ (2004)	36/255 (14.1)
Mild unilateral pelvis dilation	32 (12.5)
Moderate unilateral pelvis dilation	1 (0.04)
Enlargement kidney	1 (0.04)
Small renal cyst	1 (0.04)
Double collecting system and severe hydronephrosis	1 (0.04)
Jahnukainen et al ⁶³ (2006) ^a	23/155 (14.8)
Hydronephrosis	8 (5)
Double collecting system	11 (7)
Multicystic dysplasia	1 (0.6)
Renal hypoplasia	1 (0.6)
Solitary kidney	1 (0.6)
Horseshoe kidney	1 (0.6)
Huang et al ⁶⁴ (2008)	112/390 (28.7)
Nephromegaly	46 (11.8)
Isolated hydronephrosis	20 (5.1)
Intermittent hydronephrosis	3 (0.8)
Hydronephrosis	8 (2.1)
Hydronephrosis and hydronephrosis	3 (0.8)
Thickened bladder wall	11 (2.8)
Small kidneys	8 (2.1)
Simple ureterocele	5 (1.3)
Double collecting systems	4 (1.0)
Increased echogenicity	3 (0.8)
Horseshoe kidney	1 (0.3)
Montini et al ⁷⁹ (2009)	38/300 (13)
Dilated pelvis, ureter, or pelvis and calyces	12 (4)
Renal swelling or local parenchymal changes	10 (3.3)
Increased bladder wall or pelvic mucosa, thickness	6 (2)
Other	10 (3.3)

^a Hospitalized children with UTI.

year of age and thus had been receiving prophylaxis before random assignment. These studies were included in the meta-analysis.

Description of Included Studies

Table 10 presents characteristics of the 8 included studies.^{64,66–70,104,105} Four studies enrolled children after diagnosis of a first episode of pyelonephritis.^{64,66–68} In those 4 studies, pyelonephritis was described as fever of more than 38°C or 38.5°C and positive urine culture results. In 1 of those studies,⁶⁷ dimercaptosuccinic acid scanning results consistent with acute pyelonephritis represented an additional requirement for inclusion. The remaining studies had slightly different inclusion criteria. In the study by Craig et al⁷¹ from 2009, symptoms consistent with UTI and positive urine culture results were required for inclusion. Fever was documented for 79% of enrolled children (454 of 576 children). In the study by Brandström et al,⁷⁰ 96% of enrolled children (194 of 203 children) had pyelonephritis, defined in a similar manner as in the 6 initial studies. The remaining patients were enrolled after prenatal diagnosis of VUR. The 2 included abstracts described studies that enrolled any child with VUR and not only children who had had pyelonephritis.^{104,105} Seven of the 8 studies (all except the study by Reddy et al¹⁰⁸) reported a gender ratio. Among those studies, there were 67% girls and 33% boys. Six studies compared antimicrobial treatment with no treatment. Only 2 studies were placebo controlled, and those 2 were the only blinded studies.^{69,105} The grade of VUR among the enrolled children varied from 0 to V, but few of the children had grade V VUR.

The ages of children included in the initial meta-analyses were 0 to 18 years; therefore, some children were included who were outside the target

TABLE 10 Studies Included in Meta-analysis

Study	Study Sites	n		Age	VUR Grade	Antimicrobial Agents	Control	Follow-up Period, mo	Outcome
		VUR	No VUR						
Craig et al ¹⁰⁵ (2002)	Australia	46	0	0–3 mo	I–V	TMP-SMX	Placebo	36	UTI and renal damage
Craig et al ⁶⁹ (2009)	Australia	243	234	0–18 y	I–V	TMP-SMX	Placebo	12	Symptomatic UTI, febrile UTI, hospitalization, and renal scarring
Garin et al ⁶⁷ (2006)	Chile, Spain, United States	113	105	3 mo to 18 y	0–III	TMP-SMX/nitrofurantoin	No treatment	12	Asymptomatic UTI, cystitis, pyelonephritis, and renal scarring
Brandström et al ⁷⁰ (2010)	Sweden	203	0	1–2 y	III–IV	TMP-SMX/cefadroxil, nitrofurantoin	No treatment	48	Febrile UTI, reflux status, and renal scarring
Montini et al ⁶⁶ (2008)	Italy	128	210	2 mo to 7 y	0–III	TMP-SMX/amoxicillin-clavulanate	No treatment	12	Febrile UTI and renal scarring
Pennesi et al ⁶⁸ (2008)	Italy	100	0	0–30 mo	II–IV	TMP-SMX	No treatment	48	UTI and renal scarring
Reddy et al ¹⁰⁴ (1997)	United States	29	0	1–10 y	I–V	TMP-SMX/nitrofurantoin	No treatment	24	UTI, progression of disease, need for surgery, parental compliance
Roussey-Kesler et al ⁶⁴ (2008)	France	225	0	1–36 m	I–III	TMP-SMX	No treatment	18	Febrile and afebrile UTI

TMP-SMX indicates trimethoprim-sulfamethoxazole.

age range for this report and for whom other factors (eg, voiding and bowel habits) might have played a role. The median age of the included children, however, was not above 3 years in any of the included studies in which it was reported. Separate meta-analyses were subsequently performed for the subgroup of children who were 2 to 24 months of age. The duration of antimicrobial treatment and follow-up monitoring ranged from 12 to 48 months. The antimicrobial agents used were trimethoprim-sulfamethoxazole (1–2 or 5–10 mg/kg),^{64,68,69,105} trimethoprim-sulfamethoxazole or amoxicillin-clavulanic acid (15 mg/kg),⁶⁶ trimethoprim-sulfamethoxazole or nitrofurantoin,^{67,104} or trimethoprim-sulfamethoxazole, cefadroxil, or nitrofurantoin.⁷⁰ Urine collection methods differed among studies. Bag specimens were reported for 3 studies.^{64,66,70} In an additional 4 studies, the description of the urine collection methods did not exclude the use of bag specimens.^{67,68,104,105} Recurrent UTI was described as (1) asymptomatic bacteriuria (diagnosed through screening cultures), (2) cystitis, (3) febrile UTI, and (4) pyelonephritis (diagnosed on the basis of focal or diffuse uptake on di-

mercaptosuccinic acid scans) in the different articles.

Quality Assessment

The included studies received scores (from 2 assessors) from 7 to 26 (scale range: 0–32) with the scoring system described by Downs and Black,⁶ with a median score of 16. Score deductions resulted from lack of blinding of patients (all except 2 studies^{69,105}), lack of blinding of assessors (all except 2 studies^{69,105}), limited or no information about patients lost to follow-up monitoring (3 studies^{64,67,104}), lack of reporting of adverse effects (all except 2 studies^{66,69}), and small sample sizes. The lowest scores, 7 and 12, were received by the 2 abstracts because of lack of details in the descriptions of the methods.^{104,105}

Antimicrobial Therapy Versus No Treatment

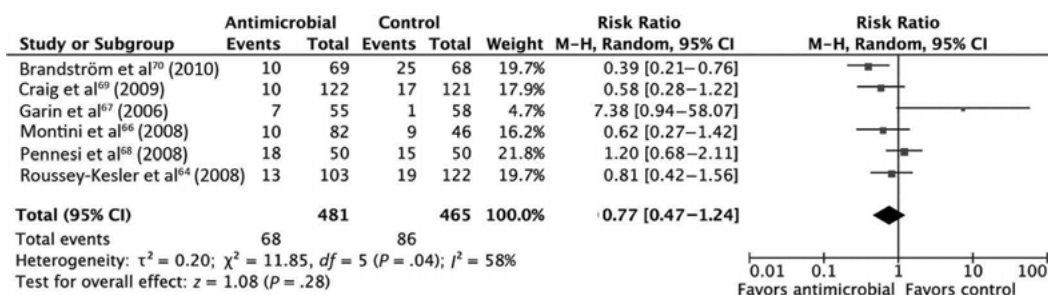
Overview of Findings

Described here are the results of several meta-analyses, subdivided according to type of recurrence (pyelonephritis versus UTI), degree of VUR (none to grade V), and patient age. In summary, antimicrobial prophylaxis does not seem to reduce significantly the

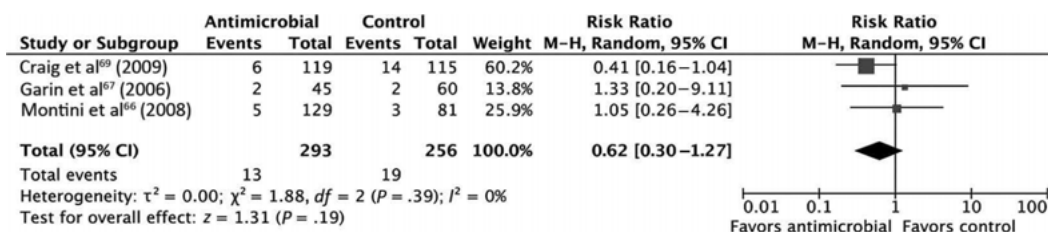
rates of recurrence of pyelonephritis, regardless of age or degree of reflux. Although prophylaxis seems to reduce significantly but only slightly the risk of UTI when all forms are included, most of this effect is attributable to reductions in rates of cystitis or asymptomatic bacteriuria, which would not be expected to lead to ongoing renal damage.

Recurrence of Pyelonephritis/Febrile UTI Among All Studied Children With VUR of Any Grade

Recurrence of pyelonephritis was reported in 6 of the 8 studies. The study by Pennesi et al⁶⁸ presented the results as recurrence of pyelonephritis, but recurrence was defined as episodes of fever or “symptoms of UTI.” When contacted, this author confirmed that all reported recurrences were characterized by fever above 38.5°C. Therefore, the article was included in the meta-analysis. With a random-effects model, there was no significant difference in rates of recurrence of pyelonephritis for children who received antimicrobial therapy and those who did not. This meta-analysis yielded a RR of 0.77 (95% CI: 0.47–1.24) (Fig 8). Heterogeneity test-

**FIGURE 8**

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children with VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

**FIGURE 9**

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children without VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

ing results were significant ($P = .04$), which indicated statistical heterogeneity between studies.

Recurrence of Pyelonephritis/ Febrile UTI Among Children of All Ages Without VUR

There was no significant difference in rates of recurrence of pyelonephritis for children without VUR who received antimicrobial therapy and those who did not. With random-effects modeling, the meta-analysis yielded a RR of 0.62 (95% CI: 0.30–1.27) (Fig 9). Heterogeneity testing results were not significant ($P = .39$). Because no difference was detected with a random-effects model and there was no statistical heterogeneity in this analysis, analysis also was conducted with a fixed-effects model. With fixed-effects modeling, the meta-analysis yielded a RR of 0.61 (95% CI: 0.31–1.23).

Recurrence of Pyelonephritis/Febrile UTI Among Children of All Ages With VUR, According to Grade

Table 11 summarizes the results of separate meta-analyses of subpopula-

TABLE 11 Combined Estimates of Effect of Antimicrobial Prophylaxis on Prevention of Pyelonephritis for All Children According to Grade of VUR

VUR Grade	No. of Children	No. of Studies	RR (95% CI) ^a
0	549	3	0.62 (0.30–1.27)
I–II	455	5	0.94 (0.49–1.80)
III	347	6	0.74 (0.42–1.29)
IV	122	3	0.69 (0.39–1.20)
V	5	1	0.40 (0.08–1.90)

^a From random-effects model.

tions from each study with different grades of VUR. None of those analyses showed a statistically significant difference in rates of recurrence with random- or fixed-effects modeling. Random-effects modeling results are presented.

Recurrence of Pyelonephritis/Febrile UTI Among Children 2 to 24 Months of Age With VUR of Any Grade

There was no significant difference in rates of recurrence of pyelonephritis for children 2 to 24 months of age with VUR who received antimicrobial agents and those who did not. With random-effects modeling, the meta-analysis yielded a RR of 0.78

(95% CI: 0.48–1.26) (Fig 10). Heterogeneity testing results were not significant ($P = .07$). With fixed-effects modeling, the meta-analysis yielded a RR of 0.79 (95% CI: 0.58–1.07). Heterogeneity testing results were not significant ($P = .07$).

Recurrence of Pyelonephritis/Febrile UTI Among Children 2 to 24 Months of Age With No VUR

There was no significant difference in rates of recurrence of pyelonephritis for children 2 to 24 months of age without VUR who received antimicrobial agents and those who did not. With random-effects modeling, the meta-analysis yielded a RR of 0.55 (95% CI:

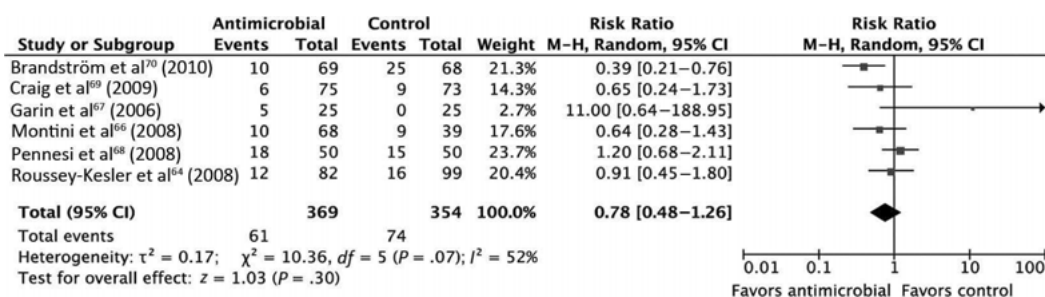


FIGURE 10

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with any grade of VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

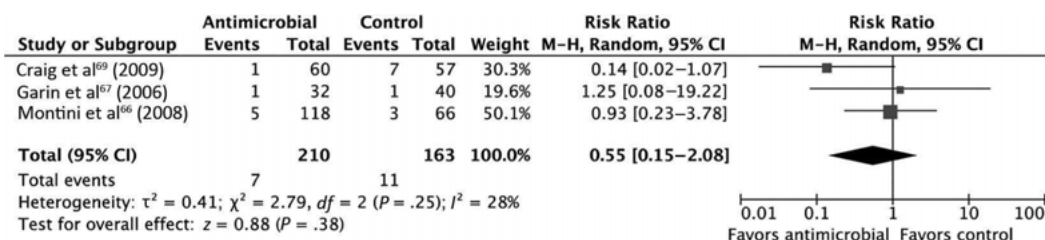


FIGURE 11

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age without VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

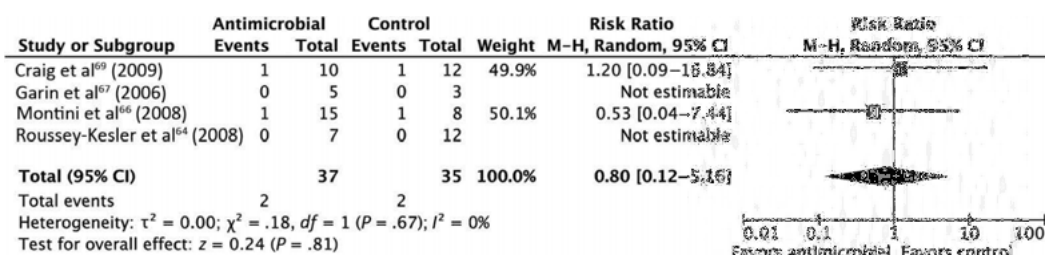


FIGURE 12

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with grade I VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

0.15–2.08) (Fig 11). Heterogeneity testing results were not significant ($P = .25$). With fixed-effects modeling, the meta-analysis yielded a RR of 0.48 (95% CI: 0.18–1.27). Heterogeneity testing results were not significant ($P = .25$).

Recurrence of Pyelonephritis/Febrile UTI Among Children 2 to 24 Months of Age According to Grade of VUR

When results were analyzed according to VUR grade, there was no significant difference in rates of recurrence of pyelonephritis for children 2 to 24 months of age who received antimicrobial agents and those who did not in any of the analyses, with

random- or fixed-effects modeling. Results of random-effects modeling are presented in Figs 12 through 16. Heterogeneity testing results were not significant in any of the analyses.

Recurrence of Any Type of UTI Among Children of All Ages With VUR of Any Grade

In this meta-analysis, in which the 2 published abstracts that never resulted in published articles were included, there was a statistically significant difference in rates of recurrence of any type of UTI for children with VUR who received antimicrobial agents and those who did not. With random-effects modeling, the meta-analysis yielded a

RR of 0.70 (95% CI: 0.51–0.96) (Fig 17). Heterogeneity testing results were not significant ($P = .20$).

The inclusion of the published abstracts^{104,105} in these meta-analyses can be criticized, because the investigators in those studies enrolled all children with VUR and not just those who had been diagnosed as having UTI; therefore, recurrent UTIs were not measured. With exclusion of the 2 abstracts from the meta-analyses for prevention of any UTI, the RR with random-effects modeling would be 0.73 (95% CI: 0.53–1.01). Heterogeneity testing results were not significant ($P = .16$).

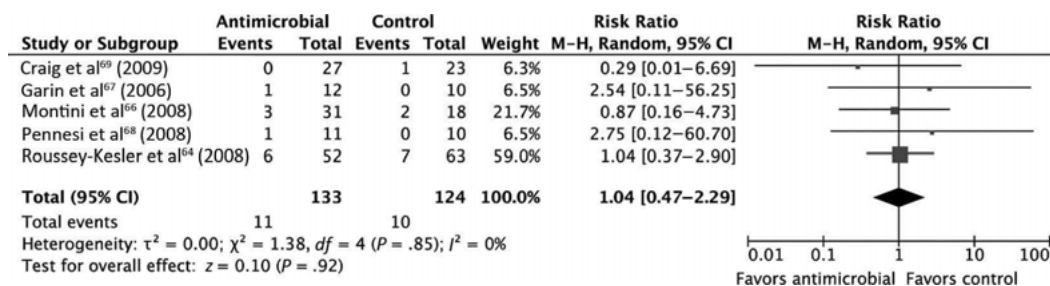


FIGURE 13

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with grade II VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

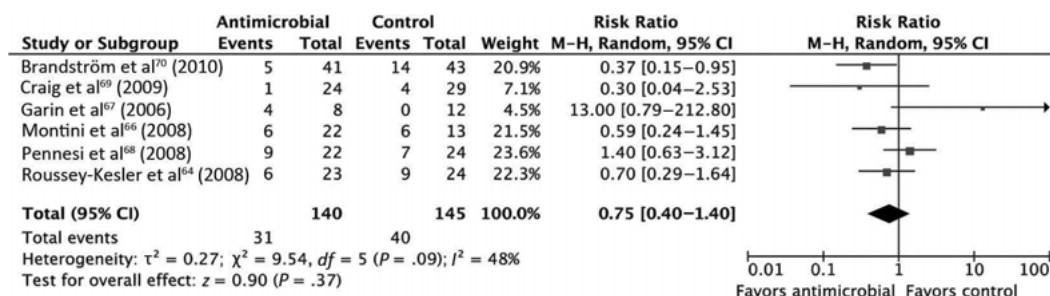


FIGURE 14

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with grade III VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

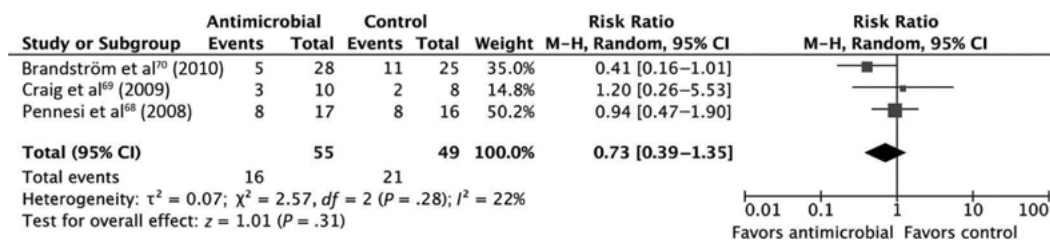


FIGURE 15

Combined estimates of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with grade IV VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

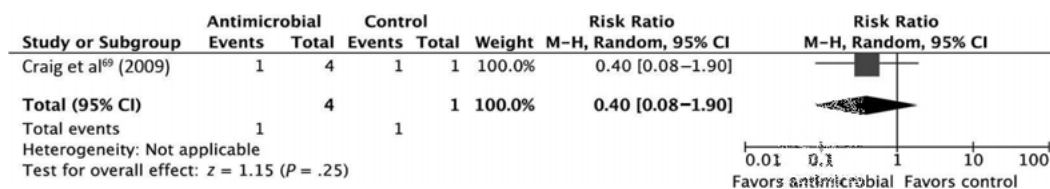


FIGURE 16

Estimate of the effect of antimicrobial prophylaxis on prevention of pyelonephritis in children 2 to 24 months of age with grade V VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

Recurrence of Any Type of UTI Among Children of All Ages Without VUR

There was no significant difference in rates of recurrence of any type of UTI for children without VUR who received

antimicrobial agents and those who did not. With random-effects modeling, the meta-analysis yielded a RR of 0.72 (95% CI: 0.43–1.20) (Fig 18). Heterogeneity testing results were not significant ($P = .37$).

Effect on Studies of Inclusion of Bag Specimens

With the exception of the study by Craig et al,⁶⁹ no studies reported that bag urine specimens were excluded. The inclusion of such specimens might

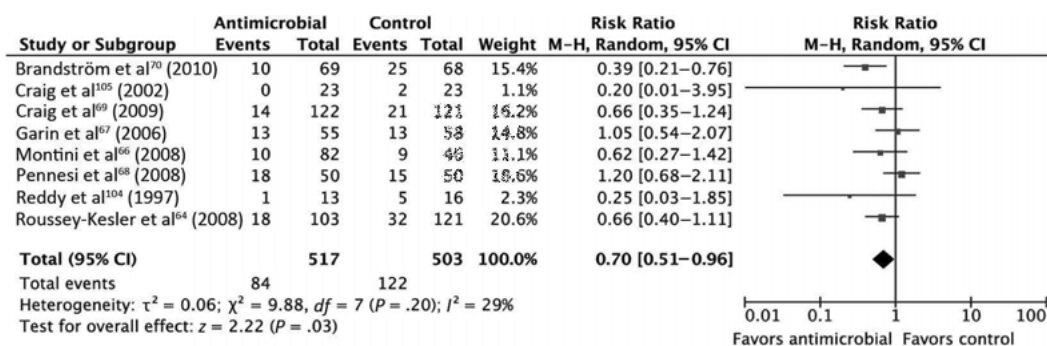


FIGURE 17

Combined estimates of the effect of antimicrobial prophylaxis on prevention of any UTI in children with any grade of VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

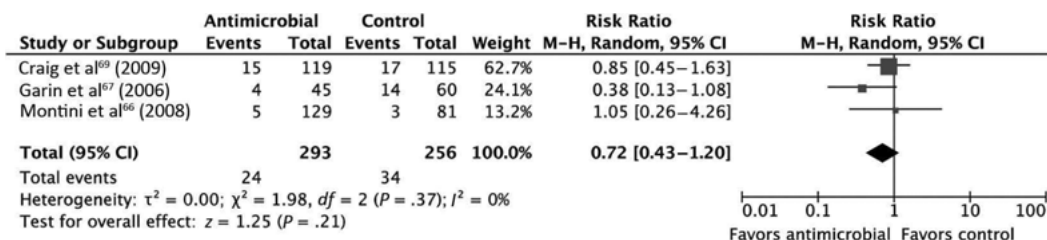


FIGURE 18

Combined estimates of the effect of antimicrobial prophylaxis on prevention of any UTI in children without VUR, from random-effects modeling. RRs and 95% CIs are shown. M-H indicates Mantel-Haenszel.

have resulted in increased numbers of false-positive urine culture results in both the antimicrobial prophylaxis and control groups, yielding a bias toward the null hypothesis in those studies.

Results of Excluded Study

The study by Lee et al⁶⁵ was excluded from the meta-analysis because it compared antimicrobial prophylaxis with probiotic treatment. A total of 120 children 13 to 36 months of age with a history of UTI and VUR of grade I to V who had been receiving trimethoprim-sulfamethoxazole once daily for 1 year were again assessed for VUR; if VUR persisted, then children were assigned randomly either to continue to receive trimethoprim-sulfamethoxazole or to receive *Lactobacillus acidophilus* twice daily for 1 additional year. The study showed no statistical difference in recurrent UTI rates between the 2 groups during the second year of follow-up monitoring.

Antimicrobial Prophylaxis and Antimicrobial Resistance

The antimicrobial resistance patterns of the pathogens isolated during UTI recurrences were assessed in 5 of the RCTs included in the meta-analyses.^{64,66,68–70} All authors concluded that UTI recurrences with antimicrobial-resistant bacteria were more common in the groups of children assigned randomly to receive antimicrobial prophylaxis. In the placebo/surveillance groups, the proportions of resistant bacteria ranged from 0% to 39%; in the antimicrobial prophylaxis groups, the proportions of resistant bacteria ranged from 53% to 100%. These results are supported by other studies in which antimicrobial prophylaxis has been shown to promote resistant organisms.^{106,107}

Surgical Intervention Versus Antimicrobial Prophylaxis

Data on the effectiveness of surgical interventions for VUR are quite limited.

To date, only 1 RCT has compared surgical intervention (only endoscopic therapy) for VUR with placebo treatment.⁷⁰ In that study, there was a statistically significant difference in the rates of recurrence of febrile UTI for girls treated with endoscopic therapy and those under surveillance (10 of 43 vs 24 of 42 girls; $P = .0014$). No such difference was noted among boys, for whom the results trended in the opposite direction (4 of 23 vs 1 of 26 boys). A meta-analysis examined the outcomes of UTIs and febrile UTIs in children assigned randomly to either reflux correction plus antimicrobial therapy or antimicrobial therapy alone.¹⁰⁸ By 2 years, the authors found no significant reduction in the risk of UTI in the surgery plus antimicrobial therapy group, compared with the antimicrobial therapy-only group (4 studies; RR: 1.07 [95% CI: 0.55–2.09]). The frequency of febrile UTIs was reported in only 2 studies. Children in the surgery plus

antimicrobial therapy group had significantly fewer febrile UTIs than did children in the antimicrobial therapy-only group between 0 and 5 years after intervention (RR: 0.43 [95% CI: 0.27–0.70]). Although there may be some promise in endoscopic interventions for children with VUR, to date there are insufficient data to show whether and for whom such interventions may be helpful.

Long-term Consequences of VUR

The link between VUR discovered after the first UTI and subsequent hypertension and end-stage renal disease remains tenuous at best. There have been no longitudinal studies monitoring children long enough to quantify these outcomes. Retrospective studies evaluated highly selected populations, and their findings might not apply to otherwise healthy children with a first UTI.^{109–112} Ecologic data from Australia demonstrated no changes in the rates of hypertension and renal failure since the widespread introduction of antimicrobial prophylaxis and ureteric reimplantation surgery for VUR in the 1960s.¹¹³

DISCUSSION

Review of the evidence regarding diagnosis and management of UTIs in 2- to 24-month-old children yields the following. First, the prevalence of UTI in febrile infants remains about the same, at ~5%. Studies have provided demographic features (age, race, and gender) and clinical characteristics (height and duration of fever, other causes of fever, and circumcision) that can help clinicians identify febrile infants whose low risk of UTI obviates the need for further evaluation.

Among children who do not receive immediate antimicrobial therapy, UTI can be ruled out on the basis of completely negative urinalysis results. For this purpose, enhanced urinalysis is preferable. However, facilities for urine microscopy with counting chambers and Gram staining may not be available in

all settings. A urine reagent strip with negative nitrite and leukocyte esterase reaction results is sufficient to rule out UTI if the pretest risk is moderate (~5%). Diagnosis of UTI is best achieved with a combination of culture and urinalysis. Cultures of urine collected through catheterization, compared with SPA, are nearly as sensitive and specific but have higher success rates and the process is less painful. Cultures of urine collected in bags have unacceptably high false-positive rates.

The previous guideline recommended VCUG after the first UTI for children between 2 and 24 months of age. The rationale for this recommendation was that antimicrobial prophylaxis among children with VUR could reduce subsequent episodes of pyelonephritis and additional renal scarring. However, evidence does not support antimicrobial prophylaxis to prevent UTI when VUR is found through VCUG. The only statistically significant effect of antimicrobial prophylaxis was in preventing UTI that included cystitis and asymptomatic bacteriuria. Statistically significant differences in the rates of febrile UTI or pyelonephritis were not seen. Moreover, VCUG is one of the most uncomfortable radiologic procedures performed with children.^{114–116}

Even if additional studies were to show a statistically significant effect of prophylaxis in preventing pyelonephritis, our point estimates suggest that the RR would be ~0.80, corresponding to a reduction in RR of 20%. If we take into account the prevalence of VUR, the risk of recurrent UTI in those children, and this modest *potential* effect, we can determine that ~100 children would need to undergo VCUG for prevention of 1 UTI in the first year. Even more striking is the fact that the evidence of benefit is the same (or better) for children with *no* VUR, which makes the benefit of VCUG more dubious. Taken in light of the marginal cost-effectiveness of the procedure found under the more-optimistic as-

sumptions in the 1999 technical report, these data argue against VCUG after the first UTI. VCUG after a second or third UTI would have a higher yield of higher grades of reflux, but the optimal care for infants with higher-grade reflux is still not clear. Ultrasonography of the kidneys, ureters, and bladder after a first UTI has poor sensitivity and only a modest yield of “actionable” findings. However, the procedure is less invasive, less uncomfortable, and less risky (in terms of radiation) than is VCUG.

There is a significant risk of renal scarring among children with febrile UTI, and some evidence suggests that early antimicrobial treatment mitigates that risk. It seems prudent to recommend early evaluation (in the 24- to 48-hour time frame) of subsequent fevers and prompt treatment of UTI to minimize subsequent renal scarring.

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The New American Academy of Pediatrics Urinary Tract Infection Guideline

This issue of *Pediatrics* includes a long-awaited update¹ of the American Academy of Pediatrics (AAP) 1999 urinary tract infection (UTI) practice parameter.² The new guideline is accompanied by a technical report³ that provides a comprehensive literature review and also a new meta-analysis, for which the authors obtained individual-level data from investigators. The result is an exceptionally evidence-based guideline that differs in important ways from the 1999 guideline and sets a high standard for transparency and scholarship.

The guideline and technical report address a logical sequence of questions that arise clinically, including (1) Which children should have their urine tested? (2) How should the sample be obtained? (3) How should UTIs be treated? (4) What imaging and follow-up are recommended after a diagnosis of UTI? and (5) How should children be followed after a UTI has been diagnosed? I will follow that same sequence in this commentary. I will mention some important areas of agreement and make other suggestions when I believe alternative recommendations are supported by available evidence.

WHICH CHILDREN SHOULD HAVE THEIR URINE TESTED?

Unlike the 1999 practice parameter, which recommended urine testing for all children aged 2 months to 2 years with unexplained fever,² the new guideline recommends selective urine testing based on the prior probability of UTI, which is an important improvement. The guideline and technical report do an admirable job summarizing the main factors that determine that prior probability (summarized in Table 1 in the clinical report). This table will help clinicians estimate whether the probability of UTI is $\geq 1\%$ or $\geq 2\%$, values that the authors suggest are reasonable thresholds for urine testing.

The guideline appropriately states that the threshold probability for urine testing is not known and that “clinicians will choose a threshold depending on factors such as their confidence that contact will be maintained through the illness. . . and comfort with diagnostic uncertainty.” However, the authors assert that this threshold is below 3%, which indicates that it is worth performing urine tests on more than 33 febrile children to identify a single UTI. This is puzzling, because the only study cited to support a specific testing threshold found that 33% of academicians and 54% of practitioners had a urine culture threshold higher than 3%.⁴

An evidence-based urine-testing threshold probability would be based on the risks and costs of urine testing compared with the benefits of diagnosing a UTI. These benefits are not known and probably are not uniform; the younger and sicker an infant is and the longer he or she has been febrile, the greater the likely benefit of diagnosing and treating a UTI. Because acute symptoms of most UTIs seem to resolve un-

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ABBREVIATIONS

AAP—American Academy of Pediatrics

UTI—urinary tract infection

VCUG—voiding cystourethrogram

VUR—vesicoureteral reflux

Opinions expressed in these commentaries are those of the author and not necessarily those of the American Academy of Pediatrics or its Committees.

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FREE

eventually, even without treatment,^{5,6} some of the impetus for diagnosing UTIs rests on the belief that doing so will reduce the risk of renal scarring and associated sequelae.⁷ This belief needs to be proven, and the benefit quantified, if a urine-testing threshold is to be evidence-based. Until then, rather than automatically testing urine on the basis of the risk factors and the 1% or 2% threshold suggested in Table 1, clinicians should continue to individualize. It seems reasonable, for example, to defer urine tests on the large number of febrile infants for whom, if their parents had called for advice, we would have estimated their probability of UTI or other serious illness to be low enough that they could be safely initially watched at home.

A potential source of confusion is that Table 1 lists “absence of another source of infection” as a risk factor, and the technical report indicates that this factor has a likelihood ratio of ~1.4 for UTI. However, the inclusion of this risk factor in the table is inconsistent with the text of the guideline, which directs clinicians to assess the likelihood of UTI in febrile infants with no apparent source for the fever. If children with an apparent source for their fever are included, the use of Table 1 could lead to excessive urine testing (eg, among infants with colds). For example, even using the 2% testing threshold, according to Table 1 all non-black uncircumcised boys younger than 24 months with any fever of any duration, even with an apparent source, would need their urine tested. I doubt that this level of urine testing is necessary or was intended by the authors of the guideline.

HOW SHOULD THE SAMPLE BE OBTAINED?

I am glad the new guideline continues to offer the option of obtaining urine for urinalyses noninvasively, but I am

not convinced that the bag urine can never be used for culture. If the urinalysis is used to select urine for culture, the prior probability may sometimes be in a range where the bag culture will be useful. For example, the technical report calculates that “with a prevalence of 5% and specificity of 70%, the positive predictive value of a positive culture obtained by bag would be 15%.” However, with the same 5% pretest probability, a positive nitrite test would raise the probability of UTI to ~75% (using the median sensitivity [58%] and specificity [99%] in the technical report). This is high enough to make the positive culture on bag urine convincing (and perhaps unnecessary).

Although bag urine cultures can lead to errors, catheterized urine cultures are not perfect¹ and urethral catheterization is painful,⁸ frightening,⁹ and risks introducing infection.¹⁰ Fortunately, if other recommendations in the guideline are followed (including the elimination of routine voiding cystourethrograms [VCUGs] and outpatient rather than inpatient antimicrobial therapy; see below), the adverse consequences of falsely positive bag cultures will be markedly attenuated.

HOW SHOULD UTIs BE TREATED?

The guideline recognizes regional variation in antimicrobial susceptibility patterns and appropriately suggests that they dictate the choice of initial treatment. However, I would adjust the choice on the basis of the clinical course rather than on sensitivity testing of the isolated uropathogen, as recommended in the guideline. At the University of California at San Francisco we have the option of a “screening” urine culture, which provides only the colony count and Gram-stain results for positive cultures (eg, “10⁵ Gram-negative rods”). We can later add identification and sensitivities of the organism in the rare instances in which

obtaining them is clinically indicated. Use of screening cultures can lead to considerable savings, because identification of organisms and antimicrobial susceptibility testing are expensive and unnecessary in the majority of cases in which patients are better within 24 hours of starting treatment.

The guideline and technical report cite good evidence that oral antimicrobial treatment is as effective as parenteral treatment and state that the choice of route of administration should be based on “practical considerations.” However, the examples they cite for when parenteral antibiotics are reasonable (eg, toxic appearance and inability to retain oral medications) seem more like clinical than practical considerations. Given equivalent estimates of efficacy and the dramatic differences in cost, the guideline could have more forcefully recommended oral treatment in the absence of clinical contraindications.

WHAT IMAGING IS INDICATED AFTER UTI?

As in the 1999 AAP guideline, the current guideline recommends a renal/bladder ultrasound examination after a first febrile UTI to rule out anatomic abnormalities (particularly obstruction) that warrant further evaluation. Although the yield of this test is low, particularly if there has been a normal third-trimester prenatal ultrasound scan, the estimated 1% to 2% yield of actionable abnormalities was believed to be sufficient to justify this noninvasive test. This may be so, but it is important to note that it is not just the yield of abnormalities but also the evidence of an advantage of early detection and cost-effectiveness that must be considered when deciding whether an ultrasound scan is indicated after the first febrile UTI, and this evidence was not reviewed.

The recommendation most dramatically different from the 1999 guideline

is that a VCUG not be routinely performed after a first febrile UTI. The main reason for this change is the accumulation of evidence casting doubt on the benefit of making a diagnosis of vesicoureteral reflux (VUR). To put these data in historical perspective, operative ureteral reimplantation was standard treatment for VUR until randomized trials found it to be no better than prophylactic antibiotics at preventing renal scarring.^{11–13} Although, as one commentator put it, “It is psychologically difficult to accept results that suggest that time-honored methods that are generally recommended and applied are of no or doubtful value,”¹⁴ ureteral reimplantation was gradually replaced with prophylactic antibiotics as standard treatment for VUR. This was not because of evidence of benefit of antibiotics but because their use was easier and less invasive than ureteral reimplantation. Finally, in the last few years, several randomized trials have investigated the efficacy of prophylactic antibiotics for children with reflux and have found little, if any, benefit.^{1,3} Thus, the risks, costs, and discomfort of the VCUG are hard to justify, because there is no evidence that patients benefit from having their VUR diagnosed.^{15–18}

The recommendation not to perform a VCUG after the first UTI is consistent with a guideline published by the

United Kingdom’s National Institute for Health and Clinical Excellence (NICE).¹⁹ However, unlike the AAP, the NICE does not recommend that VCUGs be performed routinely for recurrent UTIs in infants older than 6 months, which makes sense; the arguments against VCUGs after a first UTI still hold after a second UTI. The AAP recommendation to perform a VCUG after the second UTI is based on the increasing likelihood of detecting higher grades of reflux in children with recurrent UTIs and the belief that detecting grade V reflux is beneficial. However, the guideline appropriately recognizes that grade V reflux is rare and that the benefits of diagnosing it are still in some doubt. Therefore, the guideline suggests that parent preferences be considered in making these imaging decisions.

HOW SHOULD CHILDREN BE FOLLOWED AFTER A UTI HAS BEEN DIAGNOSED?

The guideline recommends that parents or guardians of children with confirmed UTI “seek prompt (ideally within 48 hours) medical evaluation for future febrile illnesses to ensure that recurrent infections can be detected and treated promptly.” As pointed out in the guideline, parents will ultimately make the judgment to seek medical care, and there is room for judgment here. After-hours or weekend visits would not generally be required for in-

fants who appear well, and the necessity and urgency of the visit would be expected to increase with the discomfort of the child, the height and duration of the fever, the absence of an alternative source, and the number of previous UTIs.

It should be noted that the guideline does not recommend prophylactic antibiotics to prevent UTI recurrences. This was a good decision; meta-analyses^{3,20} have revealed no significant reduction in symptomatic UTI from such prophylaxis regardless of whether VUR was present. Even in the study that showed a benefit,²¹ the absolute risk reduction for symptomatic UTI over the 1-year follow-up period was only ~6%, and there was no reduction in hospitalizations for UTI or in renal scarring. Thus, as one colleague put it, if UTI prophylaxis worked, it would offer the opportunity to “treat 16 children with antibiotics for a year to prevent treating one child with antibiotics for a week.” (A. R. Schroeder, MD, written communication, June 24, 2011).

CONCLUSIONS

I salute the authors of the new AAP UTI guideline and the accompanying technical report. Both publications represent a significant advance that should be helpful to clinicians and families dealing with this common problem.

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Urinary Tract Infection Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
— Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months
- ICD-9-CM/ICD-10-CM Coding Quick Reference for Urinary Tract Infection
- AAP Patient Education Handout
— *Urinary Tract Infections in Young Children*

Action Statement Summary

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months

Action Statement 1

If a clinician decides that a febrile infant with no apparent source for the fever requires antimicrobial therapy to be administered because of ill appearance or another pressing reason, the clinician should ensure that a urine specimen is obtained for both culture and urinalysis before an antimicrobial agent is administered; the specimen needs to be obtained through catheterization or SPA, because the diagnosis of UTI cannot be established reliably through culture of urine collected in a bag (evidence quality: A; strong recommendation).

Action Statement 2

If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI (see below for how to assess likelihood).

Action Statement 2a

If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).

Action Statement 2b

If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation). Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis. Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results positive for leukocytes or bacteria), then a urine specimen should be obtained through catheterization or SPA and cultured; if urinalysis of fresh (<1 hour since void) urine yields negative leukocyte esterase and nitrite test results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that negative urinalysis results do not rule out a UTI with certainty.

Action Statement 3

To establish the diagnosis of UTI, clinicians should require *both* urinalysis results that suggest infection (pyuria and/or bacteriuria) *and* the presence of at least 50 000 colony-forming units (CFUs) per mL of a uropathogen cultured from a urine specimen obtained through catheterization or SPA (evidence quality: C; recommendation).

Action Statement 4a

When initiating treatment, the clinician should base the choice of route of administration on practical considerations. Initiating treatment orally or parenterally is equally efficacious. The clinician should base the choice of agent on local antimicrobial sensitivity patterns (if available) and should adjust the choice according to sensitivity testing of the isolated uropathogen (evidence quality: A; strong recommendation).

Action Statement 4b

The clinician should choose 7 to 14 days as the duration of antimicrobial therapy (evidence quality: B; recommendation).

Action Statement 5

Febrile infants with UTIs should undergo renal and bladder ultrasonography (RBUS) (evidence quality: C; recommendation).

Action Statement 6a

VCUG should not be performed routinely after the first febrile UTI; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances (evidence quality B; recommendation).

Action Statement 6b

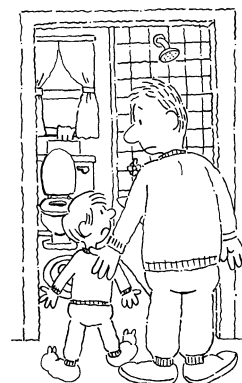
Further evaluation should be conducted if there is a recurrence of febrile UTI (evidence quality: X; recommendation).

Action Statement 7

After confirmation of UTI, the clinician should instruct parents or guardians to seek prompt medical evaluation (ideally within 48 hours) for future febrile illnesses, to ensure that recurrent infections can be detected and treated promptly (evidence quality: C; recommendation).

Coding Quick Reference for Urinary Tract Infection	
<i>ICD-9-CM</i>	<i>ICD-10-CM</i>
599.0 Urinary tract infection, site not specified	N39.0 Urinary tract infection, site not specified
771.82 Urinary tract infection, newborn	P39.3 Neonatal urinary tract infection

Urinary Tract Infections in Young Children



Urinary tract infections (UTIs) are common in young children. These infections can lead to serious health problems. UTIs may go untreated because the symptoms may not be obvious to the child or the parents. The following is information from the American Academy of Pediatrics about UTIs—what they are, how children get them, and how they are treated.

The urinary tract

The urinary tract makes and stores urine. It is made up of the kidneys, ureters, bladder, and urethra (see illustration on the next page). The kidneys produce urine. Urine travels from the kidneys down 2 narrow tubes called the ureters to the bladder. The bladder is a thin muscular bag that stores urine until it is time to empty urine out of the body. When it is time to empty the bladder, a muscle at the bottom of the bladder relaxes. Urine then flows out of the body through a tube called the urethra. The opening of the urethra is at the end of the penis in boys and above the vaginal opening in girls.

Urinary tract infections

Normal urine has no germs (bacteria). However, bacteria can get into the urinary tract from 2 sources: (1) the skin around the rectum and genitals and (2) the bloodstream from other parts of the body. Bacteria may cause infections in any or all parts of the urinary tract, including the following:

- Urethra (called urethritis)
- Bladder (called cystitis)
- Kidneys (called pyelonephritis)

UTIs are common in infants and young children. The frequency of UTIs in girls is much greater than in boys. About 3% of girls and 1% of boys will have a UTI by 11 years of age. A young child with a high fever and no other symptoms has a 1 in 20 chance of having a UTI. Uncircumcised boys have more UTIs than those who have been circumcised.

Symptoms

Symptoms of UTIs may include the following:

- Fever
- Pain or burning during urination
- Need to urinate more often, or difficulty getting urine out
- Urgent need to urinate, or wetting of underwear or bedding by a child who knows how to use the toilet
- Vomiting, refusal to eat
- Abdominal pain
- Side or back pain
- Foul-smelling urine
- Cloudy or bloody urine
- Unexplained and persistent irritability in an infant
- Poor growth in an infant

Diagnosis

If your child has symptoms of a UTI, your child's doctor will do the following:

- Ask about your child's symptoms.
- Ask about any family history of urinary tract problems.
- Ask about what your child has been eating and drinking.
- Examine your child.
- Get a urine sample from your child.

Your child's doctor will need to test your child's urine to see if there are bacteria or other abnormalities.

Ways urine is collected

Urine must be collected and analyzed to determine if there is a bacterial infection. Older children are asked to urinate into a container.

There are 3 ways to collect urine from a young child:

1. The preferred method is to place a small tube, called a catheter, through the urethra into the bladder. Urine flows through the tube into a special urine container.
2. Another method is to insert a needle through the skin of the lower abdomen to draw urine from the bladder. This is called needle aspiration.
3. If your child is very young or not yet toilet trained, the child's doctor may place a plastic bag over the genitals to collect the urine. Since bacteria on the skin can contaminate the urine and give a false test result, this method is used only to screen for infection. If an infection seems to be present, the doctor will need to collect urine through 1 of the first 2 methods in order to determine if bacteria are present.

Your child's doctor will discuss with you the best way to collect your child's urine.

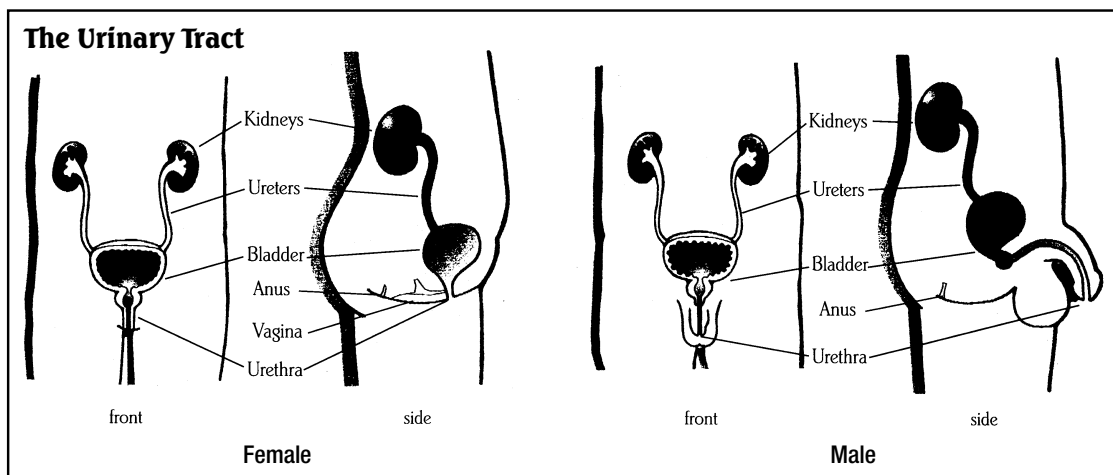
Treatment

UTIs are treated with antibiotics. The way your child receives the antibiotic depends on the severity and type of infection. Antibiotics are usually given by mouth, as liquid or pills. If your child has a fever or is vomiting and is unable to keep fluids down, the antibiotics may be put directly into a vein or injected into a muscle.

UTIs need to be treated right away to

- Get rid of the infection.
- Prevent the spread of the infection outside of the urinary tract.
- Reduce the chances of kidney damage.

Infants and young children with UTIs usually need to take antibiotics for 7 to 14 days, sometimes longer. Make sure your child takes all the medicine your child's doctor prescribes. Do not stop giving your child the medicine until the child's doctor says the treatment is finished, even if your child feels better. UTIs can return if not fully treated.



Follow-up

If the UTI occurs early in life, your child's doctor will probably want to make sure the urinary tract is normal with a kidney and bladder ultrasound. This test uses sound waves to examine the bladder and kidneys.

In addition, your child's doctor may want to make sure that the urinary tract is functioning normally and is free of any damage. Several tests are available to do this, including the following:

Voiding cystourethrogram (VCUG). A catheter is placed into the urethra and the bladder is filled with a liquid that can be seen on x-rays. This test shows whether the urine is flowing back from the bladder toward the kidneys instead of all of it coming out through the urethra as it should.

Nuclear scans. Radioactive material is injected into a vein to see if the kidneys are normal. There are many kinds of nuclear scans, each giving different information about the kidneys and bladder. The radioactive material gives no more radiation than any other kind of x-ray.

Remember

UTIs are common and most are easy to treat. Early diagnosis and prompt treatment are important because untreated or repeated infections can cause long-term medical problems. Children who have had one UTI are more likely to have another. Be sure to see your child's doctor early if your child has had a UTI in the past and has fever. Talk with your child's doctor if you suspect that your child might have a UTI.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

From your doctor

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

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SECTION 2

Endorsed Clinical Practice Guidelines

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*The American Academy of Pediatrics endorses
and accepts as its policy the following
guidelines from other organizations.*

AUTISM

Screening and Diagnosis of Autism

Quality Standards Subcommittee of the American Academy of Neurology and the Child Neurology Society

Abstract. Autism is a common disorder of childhood, affecting 1 in 500 children. Yet, it often remains unrecognized and undiagnosed until or after late preschool age because appropriate tools for routine developmental screening and screening specifically for autism have not been available. Early identification of children with autism and intensive, early intervention during the toddler and preschool years improves outcome for most young children with autism. This practice parameter reviews the available empirical evidence and gives specific recommendations for the identification of children with autism. This approach requires a dual process: 1) routine developmental surveillance and screening specifically for autism to be performed on all children to first identify those at risk for any type of atypical development, and to identify those specifically at risk for autism; and 2) to diagnose and evaluate autism, to differentiate autism from other developmental disorders. (8/00)

CEREBRAL PALSY

Diagnostic Assessment of the Child With Cerebral Palsy

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. Objective. The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society develop practice parameters as strategies for patient management based on analysis of evidence. For this parameter the authors reviewed available evidence on the assessment of a child suspected of having cerebral palsy (CP), a nonprogressive disorder of posture or movement due to a lesion of the developing brain.

Methods. Relevant literature was reviewed, abstracted, and classified. Recommendations were based on a four-tiered scheme of evidence classification.

Results. CP is a common problem, occurring in about 2 to 2.5 per 1,000 live births. In order to establish that a brain abnormality exists in children with CP that may, in turn, suggest an etiology and prognosis, neuroimaging is recommended with MRI preferred to CT (Level A). Metabolic and genetic studies should not be routinely obtained in the evaluation of the child with CP (Level B). If the clinical history or findings on neuroimaging do not determine a specific structural abnormality or if there are additional and atypical features in the history or clinical examination, metabolic and genetic testing should be considered (Level C). Detection of a brain malformation in a child with CP warrants consideration of an underlying genetic or metabolic etiology. Because the incidence of cerebral infarction is high in children with hemiplegic CP, diagnostic testing for coagulation disorders should be considered (Level B). However, there is insufficient evidence at present to be precise as to what studies should be ordered. An EEG is not recommended unless there are features sugges-

tive of epilepsy or a specific epileptic syndrome (Level A). Because children with CP may have associated deficits of mental retardation, ophthalmologic and hearing impairments, speech and language disorders, and oral-motor dysfunction, screening for these conditions should be part of the initial assessment (Level A).

Conclusions. Neuroimaging results in children with CP are commonly abnormal and may help determine the etiology. Screening for associated conditions is warranted as part of the initial evaluation. (3/04)

COMMUNITY-ACQUIRED PNEUMONIA

The Management of Community-Acquired Pneumonia (CAP) in Infants and Children Older Than 3 Months of Age

Pediatric Infectious Diseases Society and Infectious Diseases Society of America

ABSTRACT. Evidenced-based guidelines for management of infants and children with community-acquired pneumonia (CAP) were prepared by an expert panel comprising clinicians and investigators representing community pediatrics, public health, and the pediatric specialties of critical care, emergency medicine, hospital medicine, infectious diseases, pulmonology, and surgery. These guidelines are intended for use by primary care and subspecialty providers responsible for the management of otherwise healthy infants and children with CAP in both outpatient and inpatient settings. Site-of-care management, diagnosis, antimicrobial and adjunctive surgical therapy, and prevention are discussed. Areas that warrant future investigations are also highlighted. (10/11)

CONGENITAL ADRENAL HYPERPLASIA

Congenital Adrenal Hyperplasia Due to Steroid 21-hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline

The Endocrine Society

CONCLUSIONS. We recommend universal newborn screening for severe steroid 21-hydroxylase deficiency followed by confirmatory tests. We recommend that prenatal treatment of CAH continue to be regarded as experimental. The diagnosis rests on clinical and hormonal data; genotyping is reserved for equivocal cases and genetic counseling. Glucocorticoid dosage should be minimized to avoid iatrogenic Cushing's syndrome. Mineralocorticoids and, in infants, supplemental sodium are recommended in classic CAH patients. We recommend against the routine use of experimental therapies to promote growth and delay puberty; we suggest patients avoid adrenalectomy. Surgical guidelines emphasize early single-stage genital repair for severely virilized girls, performed by experienced surgeons. Clinicians should consider patients' quality of life, consulting mental health professionals as appropriate. At the transition to adulthood, we recommend monitoring for potential complications of CAH. Finally, we recommend judicious use of medication during pregnancy and in symptomatic patients with nonclassic CAH. (9/10)

DEPRESSION

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): I. Identification, Assessment, and Initial Management

Rachel A. Zuckerbrot, MD; Amy H. Cheung, MD; Peter S. Jensen, MD; Ruth E. K. Stein, MD; Danielle Laraque, MD; and GLAD-PC Steering Group

ABSTRACT. Objectives. To develop clinical practice guidelines to assist primary care clinicians in the management of adolescent depression. This first part of the guidelines addresses identification, assessment, and initial management of adolescent depression in primary care settings.

Methods. By using a combination of evidence- and consensus-based methodologies, guidelines were developed by an expert steering committee in 5 phases, as informed by (1) current scientific evidence (published and unpublished), (2) a series of focus groups, (3) a formal survey, (4) an expert consensus workshop, and (5) draft revision and iteration among members of the steering committee.

Results. Guidelines were developed for youth aged 10 to 21 years and correspond to initial phases of adolescent depression management in primary care, including identification of at-risk youth, assessment and diagnosis, and initial management. The strength of each recommendation and its evidence base are summarized. The identification, assessment, and initial management section of the guidelines includes recommendations for (1) identification of depression in youth at high risk, (2) systematic assessment procedures using reliable depression scales, patient and caregiver interviews, and Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria, (3) patient and family psychoeducation, (4) establishing relevant links in the community, and (5) the establishment of a safety plan.

Conclusions. This part of the guidelines is intended to assist primary care clinicians in the identification and initial management of depressed adolescents in an era of great clinical need and a shortage of mental health specialists but cannot replace clinical judgment; these guidelines are not meant to be the sole source of guidance for adolescent depression management. Additional research that addresses the identification and initial management of depressed youth in primary care is needed, including empirical testing of these guidelines. (11/07)

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): II. Treatment and Ongoing Management

Amy H. Cheung, MD; Rachel A. Zuckerbrot, MD; Peter S. Jensen, MD; Kareem Ghalib, MD; Danielle Laraque, MD; Ruth E. K. Stein, MD; and GLAD-PC Steering Group

ABSTRACT. Objectives. To develop clinical practice guidelines to assist primary care clinicians in the management of adolescent depression. This second part of the guidelines addresses treatment and ongoing management of adolescent depression in the primary care setting.

Methods. Using a combination of evidence- and consensus-based methodologies, guidelines were developed in 5 phases as informed by (1) current scientific evidence (published and unpublished), (2) a series of focus groups,

(3) a formal survey, (4) an expert consensus workshop, and (5) revision and iteration among members of the steering committee.

Results. These guidelines are targeted for youth aged 10 to 21 years and offer recommendations for the management of adolescent depression in primary care, including (1) active monitoring of mildly depressed youth, (2) details for the specific application of evidence-based medication and psychotherapeutic approaches in cases of moderate-to-severe depression, (3) careful monitoring of adverse effects, (4) consultation and coordination of care with mental health specialists, (5) ongoing tracking of outcomes, and (6) specific steps to be taken in instances of partial or no improvement after an initial treatment has begun. The strength of each recommendation and its evidence base are summarized.

Conclusions. These guidelines cannot replace clinical judgment, and they should not be the sole source of guidance for adolescent depression management. Nonetheless, the guidelines may assist primary care clinicians in the management of depressed adolescents in an era of great clinical need and a shortage of mental health specialists. Additional research concerning the management of youth with depression in primary care is needed, including the usability, feasibility, and sustainability of guidelines and determination of the extent to which the guidelines actually improve outcomes of youth with depression. (11/07)

DIALYSIS

Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis, 2nd Edition
Renal Physicians Association (10/10)

ENDOCARDITIS

Prevention of Infective Endocarditis: Guidelines From the American Heart Association

Walter Wilson, MD, Chair; Kathryn A. Taubert, PhD, FAHA; Michael Gewitz, MD, FAHA; Peter B. Lockhart, DDS; Larry M. Baddour, MD; Matthew Levison, MD; Ann Bolger, MD, FAHA; Christopher H. Cabell, MD, MHS; Masato Takahashi, MD, FAHA; Robert S. Baltimore, MD; Jane W. Newburger, MD, MPH, FAHA; Brian L. Strom, MD; Lloyd Y. Tani, MD; Michael Gerber, MD; Robert O. Bonow, MD, FAHA; Thomas Pallasch, DDS, MS; Stanford T. Shulman, MD, FAHA; Anne H. Rowley, MD; Jane C. Burns, MD; Patricia Ferrieri, MD; Timothy Gardner, MD, FAHA; David Goff, MD, PhD, FAHA; David T. Durack, MD, PhD

ABSTRACT. Background. The purpose of this statement is to update the recommendations by the American Heart Association (AHA) for the prevention of infective endocarditis that were last published in 1997.

Methods and Results. A writing group was appointed by the AHA for their expertise in prevention and treatment of infective endocarditis, with liaison members representing the American Dental Association, the Infectious Diseases Society of America, and the American Academy of Pediatrics. The writing group reviewed input from national and international experts on infective endocarditis. The recommendations in this document reflect analyses of relevant literature regarding procedure-related

bacteremia and infective endocarditis, in vitro susceptibility data of the most common microorganisms that cause infective endocarditis, results of prophylactic studies in animal models of experimental endocarditis, and retrospective and prospective studies of prevention of infective endocarditis. MEDLINE database searches from 1950 to 2006 were done for English-language papers using the following search terms: endocarditis, infective endocarditis, prophylaxis, prevention, antibiotic, antimicrobial, pathogens, organisms, dental, gastrointestinal, genitourinary, streptococcus, enterococcus, staphylococcus, respiratory, dental surgery, pathogenesis, vaccine, immunization, and bacteremia. The reference lists of the identified papers were also searched. We also searched the AHA online library. The American College of Cardiology/AHA classification of recommendations and levels of evidence for practice guidelines were used. The paper was subsequently reviewed by outside experts not affiliated with the writing group and by the AHA Science Advisory and Coordinating Committee.

Conclusions. The major changes in the updated recommendations include the following: (1) The Committee concluded that only an extremely small number of cases of infective endocarditis might be prevented by antibiotic prophylaxis for dental procedures even if such prophylactic therapy were 100% effective. (2) Infective endocarditis prophylaxis for dental procedures should be recommended only for patients with underlying cardiac conditions associated with the highest risk of adverse outcome from infective endocarditis. (3) For patients with these underlying cardiac conditions, prophylaxis is recommended for all dental procedures that involve manipulation of gingival tissue or the periapical region of teeth or perforation of the oral mucosa. (4) Prophylaxis is not recommended based solely on an increased lifetime risk of acquisition of infective endocarditis. (5) Administration of antibiotics solely to prevent endocarditis is not recommended for patients who undergo a genitourinary or gastrointestinal tract procedure. These changes are intended to define more clearly when infective endocarditis prophylaxis is or is not recommended and to provide more uniform and consistent global recommendations. (*Circulation*. 2007;116:1736–1754.) (5/07)

FLUORIDE

Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States
Centers for Disease Control and Prevention (8/01)

FOOD ALLERGY

Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel
National Institute of Allergy and Infectious Diseases

ABSTRACT. Food allergy is an important public health problem that affects children and adults and may be increasing in prevalence. Despite the risk of severe allergic reactions and even death, there is no current treatment for food allergy: the disease can only be managed by allergen avoidance or treatment of symptoms. The diagnosis and management of food allergy also may vary from one clinical

practice setting to another. Finally, because patients frequently confuse nonallergic food reactions, such as food intolerance, with food allergies, there is an unfounded belief among the public that food allergy prevalence is higher than it truly is. In response to these concerns, the National Institute of Allergy and Infectious Diseases, working with 34 professional organizations, federal agencies, and patient advocacy groups, led the development of clinical guidelines for the diagnosis and management of food allergy. These Guidelines are intended for use by a wide variety of health care professionals, including family practice physicians, clinical specialists, and nurse practitioners. The Guidelines include a consensus definition for food allergy, discuss comorbid conditions often associated with food allergy, and focus on both IgE-mediated and non-IgE-mediated reactions to food. Topics addressed include the epidemiology, natural history, diagnosis, and management of food allergy, as well as the management of severe symptoms and anaphylaxis. These Guidelines provide 43 concise clinical recommendations and additional guidance on points of current controversy in patient management. They also identify gaps in the current scientific knowledge to be addressed through future research. (12/10)

GASTROENTERITIS

Managing Acute Gastroenteritis Among Children: Oral Rehydration, Maintenance, and Nutritional Therapy
Centers for Disease Control and Prevention (11/03)

GASTROESOPHAGEAL REFLUX

Guidelines for Evaluation and Treatment of Gastroesophageal Reflux in Infants and Children
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

ABSTRACT. Gastroesophageal reflux (GER), defined as passage of gastric contents into the esophagus, and GER disease (GERD), defined as symptoms or complications of GER, are common pediatric problems encountered by both primary and specialty medical providers. Clinical manifestations of GERD in children include vomiting, poor weight gain, dysphagia, abdominal or substernal pain, esophagitis and respiratory disorders. The GER Guideline Committee of the North American Society for Pediatric Gastroenterology and Nutrition has formulated a clinical practice guideline for the management of pediatric GER. The GER Guideline Committee, consisting of a primary care pediatrician, two clinical epidemiologists (who also practice primary care pediatrics) and five pediatric gastroenterologists, based its recommendations on an integration of a comprehensive and systematic review of the medical literature combined with expert opinion. Consensus was achieved through Nominal Group Technique, a structured quantitative method.

The Committee examined the value of diagnostic tests and treatment modalities commonly used for the management of GERD, and how those interventions can be applied to clinical situations in the infant and older child. The guideline provides recommendations for management by the primary care provider, including evaluation, initial treatment, follow-up management and indications for

consultation by a specialist. The guideline also provides recommendations for management by the pediatric gastroenterologist.

This document represents the official recommendations of the North American Society for Pediatric Gastroenterology and Nutrition on the evaluation and treatment of gastroesophageal reflux in infants and children. The American Academy of Pediatrics has also endorsed these recommendations. The recommendations are summarized in a synopsis within the article. This review and recommendations are a general guideline and are not intended as a substitute for clinical judgment or as a protocol for the management of all patients with this problem. (2001)

GROUP B STREPTOCOCCAL DISEASE

Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines from CDC, 2010

Centers for Disease Control and Prevention

SUMMARY. Despite substantial progress in prevention of perinatal group B streptococcal (GBS) disease since the 1990s, GBS remains the leading cause of early-onset neonatal sepsis in the United States. In 1996, CDC, in collaboration with relevant professional societies, published guidelines for the prevention of perinatal group B streptococcal disease (CDC. Prevention of perinatal group B streptococcal disease: a public health perspective. *MMWR* 1996;45[No. RR-7]); those guidelines were updated and republished in 2002 (CDC. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC. *MMWR* 2002;51[No. RR-11]). In June 2009, a meeting of clinical and public health representatives was held to reevaluate prevention strategies on the basis of data collected after the issuance of the 2002 guidelines. This report presents CDC's updated guidelines, which have been endorsed by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American College of Nurse-Midwives, the American Academy of Family Physicians, and the American Society for Microbiology. The recommendations were made on the basis of available evidence when such evidence was sufficient and on expert opinion when available evidence was insufficient. The key changes in the 2010 guidelines include the following:

- expanded recommendations on laboratory methods for the identification of GBS,
- clarification of the colony-count threshold required for reporting GBS detected in the urine of pregnant women,
- updated algorithms for GBS screening and intrapartum chemoprophylaxis for women with preterm labor or preterm premature rupture of membranes,
- a change in the recommended dose of penicillin-G for chemoprophylaxis,
- updated prophylaxis regimens for women with penicillin allergy, and
- a revised algorithm for management of newborns with respect to risk for early-onset GBS disease.

Universal screening at 35–37 weeks' gestation for maternal GBS colonization and use of intrapartum antibiotic

prophylaxis has resulted in substantial reductions in the burden of early-onset GBS disease among newborns. Although early-onset GBS disease has become relatively uncommon in recent years, the rates of maternal GBS colonization (and therefore the risk for early-onset GBS disease in the absence of intrapartum antibiotic prophylaxis) remain unchanged since the 1970s. Continued efforts are needed to sustain and improve on the progress achieved in the prevention of GBS disease. There also is a need to monitor for potential adverse consequences of intrapartum antibiotic prophylaxis (e.g., emergence of bacterial antimicrobial resistance or increased incidence or severity of non-GBS neonatal pathogens). In the absence of a licensed GBS vaccine, universal screening and intrapartum antibiotic prophylaxis continue to be the cornerstones of early-onset GBS disease prevention. (11/10)

HELICOBACTER PYLORI INFECTION

Helicobacter pylori Infection in Children: Recommendations for Diagnosis and Treatment

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (11/00)

HEMATOPOIETIC STEM CELL TRANSPLANT

Guidelines for Preventing Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients

Centers for Disease Control and Prevention, Infectious Diseases Society of America, and American Society of Blood and Marrow Transplantation (10/00)

HUMAN IMMUNODEFICIENCY VIRUS

Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children

US Department of Health and Human Services

SUMMARY. This report updates the last version of the Guidelines for the Prevention and Treatment of Opportunistic Infections (OIs) in HIV-Exposed and HIV-Infected Children, published in 2009. These guidelines are intended for use by clinicians and other health-care workers providing medical care for HIV-exposed and HIV-infected children in the United States. The guidelines discuss opportunistic pathogens that occur in the United States and ones that might be acquired during international travel, such as malaria. Topic areas covered for each OI include a brief description of the epidemiology, clinical presentation, and diagnosis of the OI in children; prevention of exposure; prevention of first episode of disease; discontinuation of primary prophylaxis after immune reconstitution; treatment of disease; monitoring for adverse effects during treatment, including immune reconstitution inflammatory syndrome (IRIS); management of treatment failure; prevention of disease recurrence; and discontinuation of secondary prophylaxis after immune reconstitution. A separate document providing recommendations for prevention and treatment of OIs among HIV-infected adults and post-pubertal adolescents (*Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*) was prepared by a panel of adult HIV and infectious disease specialists (see <http://aidsinfo.nih.gov/guidelines>).

These guidelines were developed by a panel of specialists in pediatric HIV infection and infectious diseases (the Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children) from the U.S. government and academic institutions. For each OI, one or more pediatric specialists with subject-matter expertise reviewed the literature for new information since the last guidelines were published and then proposed revised recommendations for review by the full Panel. After these reviews and discussions, the guidelines underwent further revision, with review and approval by the Panel, and final endorsement by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Disease Society (PIDS), and the American Academy of Pediatrics (AAP). So that readers can ascertain how best to apply the recommendations in their practice environments, the recommendations are rated by a letter that indicates the strength of the recommendation, a Roman numeral that indicates the quality of the evidence supporting the recommendation, and where applicable, a * notation that signifies a hybrid of higher-quality adult study evidence and consistent but lower-quality pediatric study evidence.

More detailed methodologic considerations are listed in Appendix 1 (Important Guidelines Considerations), including a description of the make-up and organizational structure of the Panel, definition of financial disclosure and management of conflict of interest, funding sources for the guidelines, methods of collecting and synthesizing evidence and formulating recommendations, public commentary, and plans for updating the guidelines. The names and financial disclosures for each of the Panel members are listed in Appendices 2 and 3, respectively.

An important mode of childhood acquisition of OIs and HIV infection is from infected mothers. HIV-infected women may be more likely to have coinfections with opportunistic pathogens (e.g., hepatitis C) and more likely than women who are not HIV-infected to transmit these infections to their infants. In addition, HIV-infected women or HIV-infected family members coinfecting with certain opportunistic pathogens may be more likely to transmit these infections horizontally to their children, resulting in increased likelihood of primary acquisition of such infections in young children. Furthermore, transplacental transfer of antibodies that protect infants against serious infections may be lower in HIV-infected women than in women who are HIV-uninfected. Therefore, infections with opportunistic pathogens may affect not just HIV-infected infants but also HIV-exposed, uninfected infants. These guidelines for treating OIs in children, therefore, consider treatment of infections in all children—HIV-infected and HIV-uninfected—born to HIV-infected women.

In addition, HIV infection increasingly is seen in adolescents with perinatal infection who are now surviving into their teens and in youth with behaviorally acquired HIV infection. Guidelines for postpubertal adolescents can be found in the adult OI guidelines, but drug pharmacokinetics (PK) and response to treatment may differ in younger prepubertal or pubertal adolescents. Therefore, these

guidelines also apply to treatment of HIV-infected youth who have not yet completed pubertal development.

Major changes in the guidelines from the previous version in 2009 include:

- Greater emphasis on the importance of antiretroviral therapy (ART) for prevention and treatment of OIs, especially those OIs for which no specific therapy exists;
- Increased information about diagnosis and management of IRIS;
- Information about managing ART in children with OIs, including potential drug-drug interactions;
- Updated immunization recommendations for HIV-exposed and HIV-infected children, including pneumococcal, human papillomavirus, meningococcal, and rotavirus vaccines;
- Addition of sections on influenza, giardiasis, and isosporiasis;
- Elimination of sections on aspergillosis, bartonellosis, and HHV-6 and HHV-7 infections; and
- Updated recommendations on discontinuation of OI prophylaxis after immune reconstitution in children.

The most important recommendations are highlighted in boxed major recommendations preceding each section, and a table of dosing recommendations appears at the end of each section. The guidelines conclude with summary tables that display dosing recommendations for all of the conditions, drug toxicities and drug interactions, and 2 figures describing immunization recommendations for children aged 0 to 6 years and 7 to 18 years.

The terminology for describing use of antiretroviral (ARV) drugs for treatment of HIV infection has been standardized to ensure consistency within the sections of these guidelines and with the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*. Combination antiretroviral therapy (cART) indicates use of multiple (generally 3 or more) ARV drugs as part of an HIV treatment regimen that is designed to achieve virologic suppression; highly active antiretroviral therapy (HAART), synonymous with cART, is no longer used and has been replaced by cART; the term ART has been used when referring to use of ARV drugs for HIV treatment more generally, including (mostly historical) use of one- or two-agent ARV regimens that do not meet criteria for cART.

Because treatment of OIs is an evolving science, and availability of new agents or clinical data on existing agents may change therapeutic options and preferences, these recommendations will be periodically updated and will be available at <http://AIDSinfo.nih.gov>. (11/13)

IMMUNOCOMPROMISED HOST

2013 Infectious Diseases Society of America Clinical Practice Guidelines for the Immunization of the Immunocompromised Host

Infectious Diseases Society of America

EXECUTIVE SUMMARY. These guidelines were created to provide primary care and specialty clinicians with evidence-based guidelines for active immunization of patients with altered immunocompetence and their

household contacts in order to safely prevent vaccine-preventable infections. They do not represent the only approach to vaccination. Recommended immunization schedules for normal adults and children as well as certain adults and children at high risk for vaccine-preventable infections are updated and published annually by the Centers for Disease Control and Prevention (CDC) and partner organizations. Some recommendations have not been addressed by the Advisory Committee on Immunization Practices (ACIP) to the CDC or they deviate from recommendations. The goal of presenting these guidelines is to decrease morbidity and mortality from vaccine-preventable infections in immunocompromised patients. Summarized below are the recommendations made by the panel. Supporting tables that provide additional information are available in the electronic version. The panel followed a process used in the development of other Infectious Diseases Society of America guidelines, which included a systematic weighting of the quality of the evidence and the grade of the recommendation (Table 1). The key clinical questions and recommendations are summarized in this executive summary. A detailed description of the methods, background, and evidence summaries that support each recommendation can be found in the full text of the guidelines. (1/14)

INFLUENZA

Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America

Infectious Diseases Society of America

EXECUTIVE SUMMARY. Background. Influenza virus infection causes significant morbidity and mortality in the United States each year. The majority of persons infected with influenza virus exhibit self-limited, uncomplicated, acute febrile respiratory symptoms or are asymptomatic. However, severe disease and complications due to infection, including hospitalization and death, may occur in elderly persons, in very young persons, in persons with underlying medical conditions (including pulmonary and cardiac disease, diabetes, and immunosuppression), and in previously healthy persons. Early treatment with antiviral medications may reduce the severity and duration of symptoms, hospitalizations, and complications (otitis media, bronchitis, pneumonia), and may reduce the use of outpatient services and antibiotics, extent and quantity of viral shedding, and possibly mortality in certain populations. Vaccination is the best method for preventing influenza, but antivirals may also be used as primary or secondary means of preventing influenza transmission in certain settings.

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices and the American Academy of Pediatrics provide recommendations on the appropriate use of trivalent inactivated and live, attenuated influenza vaccines, as well as information on diagnostics and antiviral use for treatment and chemoprophylaxis. The CDC's influenza Web site (<http://www.cdc.gov/flu>) also summarizes up-to-date information on current recommendations for influenza diag-

nostic testing and antiviral use. The Infectious Diseases Society of America's (IDSA's) influenza guideline provides an evidence-based set of recommendations and background on influenza with contributions from many sources, including the CDC, the American Academy of Pediatrics, the American College of Physicians, the American Academy of Family Physicians, the Pediatric Infectious Diseases Society, the Society for Healthcare Epidemiology of America, practicing clinicians, and the IDSA, to guide decision-making on these issues. The current guideline development process included a systematic weighting of the quality of the evidence and the grade of recommendation (table 1). These guidelines apply to seasonal (interpandemic) influenza and not to avian or pandemic disease. Clinical management guidelines for sporadic human infections due to avian A (H5N1) viruses have been published by the World Health Organization. (4/09)

INTRAVASCULAR CATHETER-RELATED INFECTIONS

Guidelines for the Prevention of Intravascular Catheter-Related Infections

Society of Critical Care Medicine, Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Surgical Infection Society, American College of Chest Physicians, American Thoracic Society, American Society of Critical Care Anesthesiologists, Association for Professionals in Infection Control and Epidemiology, Infusion Nurses Society, Oncology Nursing Society, Society of Cardiovascular and Interventional Radiology, American Academy of Pediatrics, and the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention

ABSTRACT. These guidelines have been developed for practitioners who insert catheters and for persons responsible for surveillance and control of infections in hospital, outpatient, and home health-care settings. This report was prepared by a working group comprising members from professional organizations representing the disciplines of critical care medicine, infectious diseases, health-care infection control, surgery, anesthesiology, interventional radiology, pulmonary medicine, pediatric medicine, and nursing. The working group was led by the Society of Critical Care Medicine (SCCM), in collaboration with the Infectious Disease Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), Surgical Infection Society (SIS), American College of Chest Physicians (ACCP), American Thoracic Society (ATS), American Society of Critical Care Anesthesiologists (ASCCA), Association for Professionals in Infection Control and Epidemiology (APIC), Infusion Nurses Society (INS), Oncology Nursing Society (ONS), Society of Cardiovascular and Interventional Radiology (SCVIR), American Academy of Pediatrics (AAP), and the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the Centers for Disease Control and Prevention (CDC) and is intended to replace the *Guideline for Prevention of Intravascular Device-Related Infections* published in 1996. These guidelines are intended to provide evidence-based recommendations for preventing catheter-related infections. Major areas of emphasis include 1) educating and training health-care providers

who insert and maintain catheters; 2) using maximal sterile barrier precautions during central venous catheter insertion; 3) using a 2% chlorhexidine preparation for skin antisepsis; 4) avoiding routine replacement of central venous catheters as a strategy to prevent infection; and 5) using antiseptic/antibiotic impregnated short-term central venous catheters if the rate of infection is high despite adherence to other strategies (ie, education and training, maximal sterile barrier precautions, and 2% chlorhexidine for skin antisepsis). These guidelines also identify performance indicators that can be used locally by health-care institutions or organizations to monitor their success in implementing these evidence-based recommendations. (11/02)

JAUNDICE

Guideline for the Evaluation of Cholestatic Jaundice in Infants

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

ABSTRACT. For the primary care provider, cholestatic jaundice in infancy, defined as jaundice caused by an elevated conjugated bilirubin, is an uncommon but potentially serious problem that indicates hepatobiliary dysfunction. Early detection of cholestatic jaundice by the primary care physician and timely, accurate diagnosis by the pediatric gastroenterologist are important for successful treatment and a favorable prognosis. The Cholestasis Guideline Committee of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition has formulated a clinical practice guideline for the diagnostic evaluation of cholestatic jaundice in the infant. The Cholestasis Guideline Committee, consisting of a primary care pediatrician, a clinical epidemiologist (who also practices primary care pediatrics), and five pediatric gastroenterologists, based its recommendations on a comprehensive and systematic review of the medical literature integrated with expert opinion. Consensus was achieved through the Nominal Group Technique, a structured quantitative method.

The Committee examined the value of diagnostic tests commonly used for the evaluation of cholestatic jaundice and how those interventions can be applied to clinical situations in the infant. The guideline provides recommendations for management by the primary care provider, indications for consultation by a pediatric gastroenterologist, and recommendations for management by the pediatric gastroenterologist.

The Cholestasis Guideline Committee recommends that any infant noted to be jaundiced at 2 weeks of age be evaluated for cholestasis with measurement of total and direct serum bilirubin. However, breast-fed infants who can be reliably monitored and who have an otherwise normal history (no dark urine or light stools) and physical examination may be asked to return at 3 weeks of age and, if jaundice persists, have measurement of total and direct serum bilirubin at that time.

This document represents the official recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition on the evaluation of cholestatic jaundice in infants. The American Academy of Pediatrics

has also endorsed these recommendations. These recommendations are a general guideline and are not intended as a substitute for clinical judgment or as a protocol for the care of all patients with this problem. (8/04)

METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS*

Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant *Staphylococcus aureus* Infections in Adults and Children

Infectious Diseases Society of America

ABSTRACT. Evidence-based guidelines for the management of patients with methicillin-resistant *Staphylococcus aureus* (MRSA) infections were prepared by an Expert Panel of the Infectious Diseases Society of America (IDSA). The guidelines are intended for use by health care providers who care for adult and pediatric patients with MRSA infections. The guidelines discuss the management of a variety of clinical syndromes associated with MRSA disease, including skin and soft tissue infections (SSTI), bacteremia and endocarditis, pneumonia, bone and joint infections, and central nervous system (CNS) infections. Recommendations are provided regarding vancomycin dosing and monitoring, management of infections due to MRSA strains with reduced susceptibility to vancomycin, and vancomycin treatment failures. (2/11)

MIGRAINE HEADACHE

Pharmacological Treatment of Migraine Headache in Children and Adolescents

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society (12/04)

PALLIATIVE CARE

Clinical Practice Guidelines for Quality Palliative Care, Third Edition

National Consensus Project for Quality Palliative Care (2013)

RADIOLOGY

Neuroimaging of the Neonate

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. Objective. The authors reviewed available evidence on neonatal neuroimaging strategies for evaluating both very low birth weight preterm infants and encephalopathic term neonates.

Imaging for the Preterm Neonate. Routine screening cranial ultrasonography (US) should be performed on all infants of <30 weeks' gestation once between 7 and 14 days of age and should be optimally repeated between 36 and 40 weeks' postmenstrual age. This strategy detects lesions such as intraventricular hemorrhage, which influences clinical care, and those such as periventricular leukomalacia and low-pressure ventriculomegaly, which provide information about long-term neurodevelopmental outcome. There is insufficient evidence for routine MRI of all very low birth weight preterm infants with abnormal results of cranial US.

Imaging for the Term Infant. Noncontrast CT should be performed to detect hemorrhagic lesions in the encephalopathic term infant with a history of birth trauma, low hematocrit, or coagulopathy. If CT findings are inconclusive, MRI should be performed between days 2 and 8 to assess the location and extent of injury. The pattern of injury identified with conventional MRI may provide diagnostic and prognostic information for term infants with evidence of encephalopathy. In particular, basal ganglia and thalamic lesions detected by conventional MRI are associated with poor neurodevelopmental outcome. Diffusion-weighted imaging may allow earlier detection of these cerebral injuries.

Recommendations. US plays an established role in the management of preterm neonates of <30 weeks' gestation. US also provides valuable prognostic information when the infant reaches 40 weeks' postmenstrual age. For encephalopathic term infants, early CT should be used to exclude hemorrhage; MRI should be performed later in the first postnatal week to establish the pattern of injury and predict neurologic outcome. (6/02)

SEDATION AND ANALGESIA

Clinical Policy: Evidence-based Approach to Pharmacologic Agents Used in Pediatric Sedation and Analgesia in the Emergency Department

American College of Emergency Physicians (10/04)

SEIZURE

Evaluating a First Nonfebrile Seizure in Children
Quality Standards Subcommittee of the American Academy of Neurology, the Child Neurology Society, and the American Epilepsy Society

ABSTRACT. Objective. The Quality Standards Subcommittee of the American Academy of Neurology develops practice parameters as strategies for patient management based on analysis of evidence. For this practice parameter, the authors reviewed available evidence on evaluation of the first nonfebrile seizure in children in order to make practice recommendations based on this available evidence. **Methods:** Multiple searches revealed relevant literature and each article was reviewed, abstracted, and classified. Recommendations were based on a three-tiered scheme of classification of the evidence. **Results:** Routine EEG as part of the diagnostic evaluation was recommended; other studies such as laboratory evaluations and neuroimaging studies were recommended as based on specific clinical circumstances. **Conclusions:** Further studies are needed using large, well-characterized samples and standardized data collection instruments. Collection of data regarding appropriate timing of evaluations would be important. (8/00)

Treatment of the Child With a First Unprovoked Seizure
Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society develop practice parameters as strategies for patient management

based on analysis of evidence regarding risks and benefits. This parameter reviews published literature relevant to the decision to begin treatment after a child or adolescent experiences a first unprovoked seizure and presents evidence-based practice recommendations. Reasons why treatment may be considered are discussed. Evidence is reviewed concerning risk of recurrence as well as effect of treatment on prevention of recurrence and development of chronic epilepsy. Studies of side effects of anticonvulsants commonly used to treat seizures in children are also reviewed. Relevant articles are classified according to the Quality Standards Subcommittee classification scheme. Treatment after a first unprovoked seizure appears to decrease the risk of a second seizure, but there are few data from studies involving only children. There appears to be no benefit of treatment with regard to the prognosis for long-term seizure remission. Antiepileptic drugs (AED) carry risks of side effects that are particularly important in children. The decision as to whether or not to treat children and adolescents who have experienced a first unprovoked seizure must be based on a risk-benefit assessment that weighs the risk of having another seizure against the risk of chronic AED therapy. The decision should be individualized and take into account both medical issues and patient and family preference. (1/03)

STATUS EPILEPTICUS

Diagnostic Assessment of the Child With Status Epilepticus (An Evidence-based Review)

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. Objective. To review evidence on the assessment of the child with status epilepticus (SE).

Methods. Relevant literature were reviewed, abstracted, and classified. When data were missing, a minimum diagnostic yield was calculated. Recommendations were based on a four-tiered scheme of evidence classification.

Results. Laboratory studies (Na⁺ or other electrolytes, Ca⁺⁺, glucose) were abnormal in approximately 6% and are generally ordered as routine practice. When blood or spinal fluid cultures were done on these children, blood cultures were abnormal in at least 2.5% and a CNS infection was found in at least 12.8%. When antiepileptic drug (AED) levels were ordered in known epileptic children already taking AEDs, the levels were low in 32%. A total of 3.6% of children had evidence of ingestion. When studies for inborn errors of metabolism were done, an abnormality was found in 4.2%. Epileptiform abnormalities occurred in 43% of EEGs of children with SE and helped determine the nature and location of precipitating electroconvulsive events (8% generalized, 16% focal, and 19% both). Abnormalities on neuroimaging studies that may explain the etiology of SE were found in at least 8% of children.

Recommendations. Although common clinical practice is that blood cultures and lumbar puncture are obtained if there is a clinical suspicion of a systemic or CNS infection, there are insufficient data to support or refute recommendations as to whether blood cultures or lumbar

puncture should be done on a routine basis in children in whom there is no clinical suspicion of a systemic or CNS infection (Level U). AED levels should be considered when a child with treated epilepsy develops SE (Level B). Toxicology studies and metabolic studies for inborn errors of metabolism may be considered in children with SE when there are clinical indicators for concern or when the initial evaluation reveals no etiology (Level C). An EEG may be considered in a child with SE as it may be helpful in determining whether there are focal or generalized epileptiform abnormalities that may guide further testing for the etiology of SE, when there is a suspicion of pseudostatus epilepticus (nonepileptic SE), or nonconvulsive SE, and may guide treatment (Level C). Neuroimaging may be considered after the child with SE has been stabilized if there are clinical indications or if the etiology is unknown (Level C). There is insufficient evidence to support or refute routine neuroimaging in a child presenting with SE (Level U). (11/06)

TOBACCO USE

Treating Tobacco Use and Dependence: 2008 Update
US Department of Health and Human Services

ABSTRACT. *Treating Tobacco Use and Dependence: 2008 Update*, a Public Health Service-sponsored Clinical Practice Guideline, is a product of the Tobacco Use and Dependence Guideline Panel ("the Panel"), consortium representatives, consultants, and staff. These 37 individuals were charged with the responsibility of identifying effective, experimentally validated tobacco dependence treatments and practices. The updated Guideline was sponsored by a consortium of eight Federal Government and nonprofit organizations: the Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Drug Abuse (NIDA); American Legacy Foundation; Robert Wood Johnson Foundation (RWJF); and University of Wisconsin School of Medicine and Public Health's Center for Tobacco Research and Intervention (UW-CTRI). This Guideline is an updated version of the 2000 *Treating Tobacco Use and Dependence: Clinical Practice Guideline* that was sponsored by the U.S. Public Health Service, U. S. Department of Health and Human Services.

An impetus for this Guideline update was the expanding literature on tobacco dependence and its treatment. The original 1996 Guideline was based on some 3,000 articles on tobacco treatment published between 1975 and 1994. The 2000 Guideline entailed the collection and screening of an additional 3,000 articles published between 1995 and 1999. The 2008 Guideline update screened an additional 2,700 articles; thus, the present Guideline update reflects the distillation of a literature base of more than 8,700 research articles. Of course, this body of research was further reviewed to identify a much smaller group of articles that served as the basis for focused Guideline data analyses and review.

This Guideline contains strategies and recommendations designed to assist clinicians; tobacco dependence treatment specialists; and health care administrators,

insurers, and purchasers in delivering and supporting effective treatments for tobacco use and dependence. The recommendations were made as a result of a systematic review and meta-analysis of 11 specific topics identified by the Panel (proactive quitlines; combining counseling and medication relative to either counseling or medication alone; varenicline; various medication combinations; long-term medications; cessation interventions for individuals with low socioeconomic status/limited formal education; cessation interventions for adolescent smokers; cessation interventions for pregnant smokers; cessation interventions for individuals with psychiatric disorders, including substance use disorders; providing cessation interventions as a health benefit; and systems interventions, including provider training and the combination of training and systems interventions). The strength of evidence that served as the basis for each recommendation is indicated clearly in the Guideline update. A draft of the Guideline update was peer reviewed prior to publication, and the input of 81 external reviewers was considered by the Panel prior to preparing the final document. In addition, the public had an opportunity to comment through a *Federal Register* review process. The key recommendations of the updated Guideline, *Treating Tobacco Use and Dependence: 2008 Update*, based on the literature review and expert Panel opinion, are as follows:

Ten Key Guideline Recommendations

The overarching goal of these recommendations is that clinicians strongly recommend the use of effective tobacco dependence counseling and medication treatments to their patients who use tobacco, and that health systems, insurers, and purchasers assist clinicians in making such effective treatments available.

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.
3. Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.
4. Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this Guideline.
5. Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt:
 - Practical counseling (problem solving/skills training)
 - Social support delivered as part of treatment

6. Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking—except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).
 - Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline
 - Clinicians also should consider the use of certain combinations of medications identified as effective in this Guideline.
7. Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, both clinicians and health care delivery systems should ensure patient access to quitlines and promote quitline use.
9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

The updated Guideline is divided into seven chapters that provide an overview, including methods (Chapter 1); information on the assessment of tobacco use (Chapter 2); clinical interventions, both for patients willing and unwilling to make a quit attempt at this time (Chapter 3); intensive interventions (Chapter 4); systems interventions for health care administrators, insurers, and purchasers (Chapter 5); the scientific evidence supporting the Guideline recommendations (Chapter 6); and information relevant to specific populations and other topics (Chapter 7).

A comparison of the findings of the updated Guideline with the 2000 Guideline reveals the considerable progress made in tobacco research over the brief period separating these two publications. Tobacco dependence increasingly is recognized as a chronic disease, one that typically requires ongoing assessment and repeated intervention. In addition, the updated Guideline offers the clinician many more effective treatment strategies than were identified in the original Guideline. There now are seven different first-line effective agents in the smoking cessation pharmacopoeia, allowing the clinician and patient many different medication options. In addition, recent evidence provides even stronger support for counseling (both when used alone and with other treatments) as an effective tobacco cessation strategy; counseling adds to the effectiveness of tobacco cessation medications, quitline counseling is an effective intervention with a broad reach, and counseling increases tobacco cessation among adolescent smokers.

Finally, there is increasing evidence that the success of any tobacco dependence treatment strategy cannot be divorced from the health care system in which it is embedded. The updated Guideline contains new evidence that health care policies significantly affect the likelihood that smokers will receive effective tobacco dependence treatment and successfully stop tobacco use. For instance, making tobacco dependence treatment a covered benefit of insurance plans increases the likelihood that a tobacco user will receive treatment and quit successfully. Data strongly indicate that effective tobacco interventions require coordinated interventions. Just as the clinician must intervene with his or her patient, so must the health care administrator, insurer, and purchaser foster and support tobacco intervention as an integral element of health care delivery. Health care administrators and insurers should ensure that clinicians have the training and support to deliver consistent, effective intervention to tobacco users.

One important conclusion of this Guideline update is that the most effective way to move clinicians to intervene is to provide them with information regarding multiple effective treatment options and to ensure that they have ample institutional support to use these options. Joint actions by clinicians, administrators, insurers, and purchasers can encourage a culture of health care in which failure to intervene with a tobacco user is inconsistent with standards of care. (5/08)

VESICoureTERAL REFLUX

Report on the Management of Primary Vesicoureteral Reflux in Children

American Urological Association (5/97)

SECTION 3

Affirmation of Value Clinical Practice Guidelines

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These guidelines are not endorsed as policy of the American Academy of Pediatrics (AAP). Documents that lack a clear description of the process for identifying, assessing, and incorporating research evidence are not eligible for AAP endorsement as practice guidelines. However, such documents may be of educational value to members of the AAP.

ASTHMA

Environmental Management of Pediatric Asthma:
Guidelines for Health Care Providers
National Environmental Education Foundation

INTRODUCTION (EXCERPT). These guidelines are the product of a new Pediatric Asthma Initiative aimed at integrating environmental management of asthma into pediatric health care. This document outlines competencies in environmental health relevant to pediatric asthma that should be mastered by primary health care providers, and outlines the environmental interventions that should be communicated to patients.

These environmental management guidelines were developed for pediatricians, family physicians, internists, pediatric nurse practitioners, pediatric nurses, and physician assistants. In addition, these guidelines should be integrated into respiratory therapists' and licensed case/care (LICSW) management professionals' education and training.

The guidelines contain three components:

- **Competencies:** An outline of the knowledge and skills that health care providers and health professional students should master and demonstrate in order to incorporate management of environmental asthma triggers into pediatric practice.
- **Environmental History Form:** A quick, easy, user-friendly document that can be utilized as an intake tool by the health care provider to help determine pediatric patients' environmental asthma triggers.
- **Environmental Intervention Guidelines:** Follow-up questions and intervention solutions to environmental asthma triggers. (8/05)

PALLIATIVE CARE AND HOSPICE

Standards of Practice for Pediatric Palliative Care
and Hospice

National Hospice and Palliative Care Organization (2/09)

SLEEP APNEA

Practice Guidelines for the Perioperative Management of
Patients with Obstructive Sleep Apnea

American Society of Anesthesiologists (5/06)

TURNER SYNDROME

Care of Girls and Women With Turner Syndrome:
A Guideline of the Turner Syndrome Study Group
Turner Syndrome Consensus Study Group

ABSTRACT. Objectives. The objective of this work is to provide updated guidelines for the evaluation and treatment of girls and women with Turner syndrome (TS).

Participants. The Turner Syndrome Consensus Study Group is a multidisciplinary panel of experts with relevant clinical and research experience with TS that met in Bethesda, Maryland, April 2006. The meeting was supported by the National Institute of Child Health and unrestricted educational grants from pharmaceutical companies.

Evidence. The study group used peer-reviewed published information to form its principal recommendations. Expert opinion was used where good evidence was lacking.

Consensus. The study group met for 3 d to discuss key issues. Breakout groups focused on genetic, cardiological, auxological, psychological, gynecological, and general medical concerns and drafted recommendations for presentation to the whole group. Draft reports were available for additional comment on the meeting web site. Synthesis of the section reports and final revisions were reviewed by e-mail and approved by whole-group consensus.

Conclusions. We suggest that parents receiving a prenatal diagnosis of TS be advised of the broad phenotypic spectrum and the good quality of life observed in TS in recent years. We recommend that magnetic resonance angiography be used in addition to echocardiography to evaluate the cardiovascular system and suggest that patients with defined cardiovascular defects be cautioned in regard to pregnancy and certain types of exercise. We recommend that puberty should not be delayed to promote statural growth. We suggest a comprehensive educational evaluation in early childhood to identify potential attention-deficit or nonverbal learning disorders. We suggest that caregivers address the prospect of premature ovarian failure in an open and sensitive manner and emphasize the critical importance of estrogen treatment for feminization and for bone health during the adult years. All individuals with TS require continued monitoring of hearing and thyroid function throughout the lifespan. We suggest that adults with TS be monitored for aortic enlargement, hypertension, diabetes, and dyslipidemia. (1/07)

SECTION 4

2014 Policies

From the American Academy of Pediatrics

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- ***Policy Statements***

*ORGANIZATIONAL PRINCIPLES TO GUIDE AND DEFINE THE CHILD HEALTH CARE SYSTEM
AND TO IMPROVE THE HEALTH OF ALL CHILDREN*

- ***Clinical Reports***

GUIDANCE FOR THE CLINICIAN IN RENDERING PEDIATRIC CARE

- ***Technical Reports***

BACKGROUND INFORMATION TO SUPPORT AMERICAN ACADEMY OF PEDIATRICS POLICY

*Includes policy statements, clinical reports, and technical reports
published between January 1, 2014, and January 1, 2015.*

INTRODUCTION

This section of *Pediatric Clinical Practice Guidelines & Policies: A Compendium of Evidence-based Research for Pediatric Practice* is composed of policy statements, clinical reports, and technical reports issued by the American Academy of Pediatrics (AAP) and is designed as a quick reference tool for AAP members, AAP staff, and other interested parties. Section 4 includes the full text of all AAP policies published in 2014. Section 5 is a compilation of all active AAP statements (through January 1, 2015) arranged alphabetically, with abstracts where applicable. A committee index (Appendix 1) and subject index are also available. The companion CD-ROM contains the full text of all current policy statements, clinical reports, and technical reports (through January 1, 2015). These materials should help answer questions that arise about the AAP position on child health care issues. **However, remember that AAP policy statements, clinical reports, and technical reports do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.**

Policy statements have been written by AAP committees, councils, task forces, or sections and approved by the AAP Board of Directors. Most of these statements have appeared previously in *Pediatrics*, *AAP News*, or *News & Comments* (the forerunner of *AAP News*).

This section does not contain all AAP policies. It does not include

- Press releases.
- Motions and resolutions that were approved by the Board of Directors. These can be found in the Board of Directors' minutes.
- Policies in manuals, pamphlets, booklets, or other AAP publications. These items can be ordered through the AAP. To order, visit shop.aap.org/books/ or call toll-free 888/227-1770.
- Testimony before Congress or government agencies.

All policy statements, clinical reports, and technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time. Please check the American Academy of Pediatrics Web site at www.aap.org for up-to-date reaffirmations, revisions, and retirements..

2014 Recommendations for Pediatric Preventive Health Care

.....

- *Policy Statement*

POLICY STATEMENT

2014 Recommendations for Pediatric Preventive Health Care

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www.pediatrics.org/cgi/doi/10.1542/peds.2013-4096

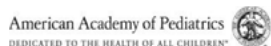
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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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*Dr Curry serves as the Committee on Practice and Ambulatory Medicine liaison to Bright Futures and is a member of the Bright Futures Steering Committee.



2014 Recommendations for Preventive Pediatric Health Care

Bright Futures/American Academy of Pediatrics



Each child and family is unique; therefore, these Recommendations for Preventive Pediatric Health Care are designed for the care of children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in satisfactory fashion. Additional visits may become necessary if circumstances suggest variations from normal.

Developmental, psychosocial, and chronic disease issues for children and adolescents may require frequent counseling and treatment visits separate from preventive care visits.

These guidelines represent a consensus by the American Academy of Pediatrics (AAP) and Bright Futures. The AAP continues to emphasize the great importance of continuity of care in comprehensive health supervision and the need to avoid fragmentation of care.

Refer to the specific guidance by age as listed in *Bright Futures* guidelines (Hagan JF, Shaw JS, Duncan PM, eds. *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents*. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008).

The recommendations in this statement do not indicate an exclusive course of treatment or standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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	INFANCY								EARLY CHILDHOOD							MIDDLE CHILDHOOD						ADOLESCENCE										
AGE ¹	Prenatal ²	Newborn ³	3-5 d ⁴	By 1 mo	2 mo	4 mo	6 mo	9 mo	12 mo	15 mo	18 mo	24 mo	30 mo	3 y	4 y	5 y	6 y	7 y	8 y	9 y	10 y	11 y	12 y	13 y	14 y	15 y	16 y	17 y	18 y	19 y	20 y	21 y
HISTORY (Initial/Interval)	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
MEASUREMENTS																																
Length/Height and Weight	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Head Circumference	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Weight for Length	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Body Mass Index ⁵												●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Blood Pressure ⁶		★	★	★	★	★	★	★	★	★	★	★	★	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
SENSORY SCREENING																																
Vision	★	★	★	★	★	★	★	★	★	★	★	★	★	● ⁷	●	●	●	★	●	★	●	★	●	★	★	●	★	★	●	★	★	★
Hearing	● ⁸	★	★	★	★	★	★	★	★	★	★	★	★	●	●	●	●	★	●	★	●	★	★	★	★	★	★	★	★	★	★	★
DEVELOPMENTAL/BEHAVIORAL ASSESSMENT																																
Developmental Screening ⁹								●			●		●																			
Autism Screening ¹⁰											●	●																				
Developmental Surveillance	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Psychosocial/Behavioral Assessment	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Alcohol and Drug Use Assessment ¹¹											●	●	●	●	●	●	●	●	●	●	●	●	★	★	★	★	★	★	★	★	★	★
Depression Screening ¹²																						●	●	●	●	●	●	●	●	●	●	●
PHYSICAL EXAMINATION ¹³	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
PROCEDURES ¹⁴																																
Newborn Blood Screening ¹⁵	←	●	→																													
Critical Congenital Heart Defect Screening ¹⁶	●								●		●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Immunization ¹⁷	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hematocrit or Hemoglobin ¹⁸						★			● or ★ ²⁰	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★
Lead Screening ¹⁹							★	★	● or ★ ²⁰	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★
Tuberculosis Testing ²¹				★					★			● or ★ ²⁰	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★
Dyslipidemia Screening ²²												★			★		★		★	★	★	→	★	★	★	★	★	★	→	●	→	
STI/HIV Screening ²³																						★	★	★	★	★	★	★	★	★	★	★
Cervical Dysplasia Screening ²⁴																																●
ORAL HEALTH ²⁵								★	★	● or ★	● or ★	● or ★	● or ★	●			●															
ANTICIPATORY GUIDANCE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

- If a child comes under care for the first time at any point on the schedule, or if any items are not accomplished at the suggested age, the schedule should be brought up to date at the earliest possible time.
- A prenatal visit is recommended for parents who are at high risk, for first-time parents, and for those who request a conference. The prenatal visit should include anticipatory guidance, pertinent medical history, and a discussion of benefits of breastfeeding and planned method of feeding, per the 2009 AAP statement "The Prenatal Visit" (<http://pediatrics.aappublications.org/content/124/4/1227.full>).
- Every infant should have a newborn evaluation after birth, and breastfeeding should be encouraged (instruction and support should be offered).
- Every infant should have an evaluation within 3 to 5 days of birth and within 48 to 72 hours after discharge from the hospital to include evaluation for feeding and jaundice. Breastfeeding infants should receive formal breastfeeding evaluation, and their mothers should receive encouragement and instruction, as recommended in the 2012 AAP statement "Breastfeeding and the Use of Human Milk" (<http://pediatrics.aappublications.org/content/129/3/582.full>). Newborn infants discharged less than 48 hours after delivery must be examined within 48 hours of discharge, per the 2010 AAP statement "Hospital Stay for Healthy Term Newborns" (<http://pediatrics.aappublications.org/content/125/2/405.full>).
- Screen, per the 2007 AAP statement "Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report" (http://pediatrics.aappublications.org/content/120/Supplement_4/S164.full).
- Blood pressure measurement in infants and children with specific risk conditions should be performed at visits before age 3 years.
- If the patient is uncooperative, rescreen within 6 months, per the 2007 AAP statement "Eye Examination in Infants, Children, and Young Adults by Pediatricians" (<http://pediatrics.aappublications.org/content/111/4/902.abstract>).
- All newborns should be screened, per the AAP statement "New 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs" (<http://pediatrics.aappublications.org/content/120/4/998.full>).
- See 2006 AAP statement "Identifying Infants and Young Children With Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening" (<http://pediatrics.aappublications.org/content/118/1/405.full>).
- Screening should occur per the 2007 AAP statement "Identification and Evaluation of Children with Autism Spectrum Disorders" (<http://pediatrics.aappublications.org/content/120/5/1183.full>).

- A recommended screening tool is available at <http://www.caesar-boston.org/CRAFFT/index.php>.
- Recommended screening using the Patient Health Questionnaire (PHQ-2) or other tools available in the GLAD-PC toolkit and at http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Documents/MH_ScreeningChart.pdf.
- At each visit, age-appropriate physical examination is essential, with infant totally unclothed and older children undressed and suitably draped. See 2011 AAP statement "Use of Chaperones During the Physical Examination of the Pediatric Patient" (<http://pediatrics.aappublications.org/content/127/5/991.full>).
- These may be modified, depending on entry point into schedule and individual need.
- The Recommended Uniform Newborn Screening Panel (<http://www.hhsa.gov/advisory-committees/ncmb/advisory-panel/recommended-panel/uniform-screening-panel.pdf>), as determined by The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, and state newborn screening laws/regulations (<http://genes-c-usa.hhsa.gov/sites/genes-c-usa/files/ncmborders.pdf>), establish the criteria for and coverage of newborn screening procedures and programs. Follow-up must be provided, as appropriate, by the pediatrician.
- Screening for critical congenital heart disease using pulse oximetry should be performed in newborns, after 24 hours of age, before discharge from the hospital, per the 2011 AAP statement "Endorsement of Health and Human Services Recommendation for Pulse Oximetry Screening for Critical Congenital Heart Disease" (<http://pediatrics.aappublications.org/content/129/1/190.full>).
- Schedules, per the AAP Committee on Infectious Diseases, are available at: <http://aapredbook.aappublications.org/site/resources/zschedules.shtml>. Every visit should be an opportunity to update and complete a child's immunizations.
- See 2010 AAP statement "Diagnosis and Prevention of Iron Deficiency and Iron Deficiency Anemia in Infants and Young Children (0-3 Years of Age)" (<http://pediatrics.aappublications.org/content/126/5/1040.full>).
- For children at risk of lead exposure, see the 2012 CDC Advisory Committee on Childhood Lead Poisoning Prevention statement "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention" (http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_030712.pdf).

- Perform risk assessments or screenings as appropriate, based on universal screening requirements for patients with Medicaid or in high prevalence areas.
- Tuberculosis testing per recommendations of the Committee on Infectious Diseases, published in the current edition of *Red Book: Report of the Committee on Infectious Diseases*. Testing should be performed on recognition of high-risk factors.
- See AAP-endorsed 2011 guidelines from the National Heart Blood and Lung Institute, "Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents" (http://www.nhlbi.nih.gov/guidelines/cvdr_ped/index.htm).
- Adolescents should be screened for sexually transmitted infections (STIs) per recommendations in the current edition of the *AAP Red Book: Report of the Committee on Infectious Diseases*. Additionally, all adolescents should be screened for HIV according to the AAP statement (<http://pediatrics.aappublications.org/content/128/5/1023.full>) once between the ages of 16 and 18, making every effort to preserve confidentiality of the adolescent. Those at increased risk of HIV infection, including those who are sexually active, participate in injection drug use, or are being tested for other STIs, should be tested for HIV and reassessed annually.
- See USPSTF recommendations (<http://www.uspreventiveservicestaskforce.org/uspstf/uspserv.htm>). Indications for pelvic examinations prior to age 21 are noted in the 2010 AAP statement "Gynecologic Examination for Adolescents in the Pediatric Office Setting" (<http://pediatrics.aappublications.org/content/126/3/580.full>).
- Refer to a dental home, if available. If not available, perform a risk assessment (<http://www2.aap.org/oralhealth/docs/RiskAssessmentTool.pdf>). If primary water source is deficient in fluoride, consider oral fluoride supplementation. For those at high risk, consider application of fluoride varnish for caries prevention. See 2008 AAP statement "Preventive Oral Health Intervention for Pediatricians" (<http://pediatrics.aappublications.org/content/122/6/1387.full>) and 2009 AAP statement "Oral Health Risk Assessment: Timing and Establishment of the Dental Home" (<http://pediatrics.aappublications.org/content/111/5/1113.full>).

KEY ● = to be performed ★ = risk assessment to be performed with appropriate action to follow, if positive ← ● → = range during which a service may be provided

Summary of changes made to the 2014 AAP Recommendations for Preventive Pediatric Health Care (Periodicity Schedule)

Changes to Developmental/Behavioral Assessment

- **Alcohol and Drug Use Assessment-** Information regarding a recommended screening tool (CRAFTT) was added.
- **Depression-** Screening for depression at ages 11 through 21 has been added, along with suggested screening tools.

Changes to Procedures

- **Dyslipidemia screening-** An additional screening between 9 and 11 years of age has been added. The reference has been updated to the AAP-endorsed National Heart Blood and Lung Institute policy (http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm).
- **Hematocrit or hemoglobin-** A risk assessment has been added at 15 and 30 months. The reference has been updated to the current AAP policy (<http://pediatrics.aappublications.org/content/126/5/1040.full>).
- **STI/HIV screening-** A screen for HIV has been added between 16 and 18 years. Information on screening adolescents for HIV has been added in the footnotes. STI screening now references recommendations made in the AAP Red Book. This category was previously titled "STI Screening."
- **Cervical dysplasia-** Adolescents should no longer be routinely screened for cervical dysplasia until age 21. Indications for pelvic exams prior to age 21 are noted in the 2010 AAP statement "Gynecologic Examination for Adolescents in the Pediatric Office Setting" (<http://pediatrics.aappublications.org/content/126/3/583.full>).
- **Critical Congenital Heart Disease-** Screening for critical congenital heart disease using pulse oximetry should be performed in newborns, after 24 hours of age, before discharge from the hospital, per the 2011 AAP statement, "Endorsement of Health and Human Services Recommendation for Pulse Oximetry Screening for Critical Congenital Heart Disease" (<http://pediatrics.aappublications.org/content/129/1/190.full>).

For several recommendations, the AAP Policy has been updated since 2007 but there have been no changes in the timing of recommendations on the Periodicity Schedule. These include:

- Footnote 2- The Prenatal Visit (2009): <http://pediatrics.aappublications.org/content/124/4/1227.full>
- Footnote 4- Breastfeeding and the Use of Human Milk (2012): <http://pediatrics.aappublications.org/content/129/3/e827.full> and Hospital Stay for Healthy Term Newborns (2010): <http://pediatrics.aappublications.org/content/125/2/405.full>
- Footnote 8- Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs (2007): <http://pediatrics.aappublications.org/content/120/4/898.full>
- Footnote 10- Identification and Evaluation of Children with Autism Spectrum Disorders (2007): <http://pediatrics.aappublications.org/content/120/5/1183.full>
- Footnote 17- Immunization Schedules (2013): <http://aapredbook.aappublications.org/site/resources/IZSchedule0-6yrs.pdf>, <http://aapredbook.aappublications.org/site/resources/IZSchedule7-18yrs.pdf>, and <http://aapredbook.aappublications.org/site/resources/IZScheduleCatchup.pdf>
- Footnote 19- CDC Advisory Committee on Childhood Lead Poisoning Prevention statement "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention" (2012): http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_030712.pdf
- Footnote 22- AAP-endorsed guideline "Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents" (2011): http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm
- Footnote 25- Preventive Oral Health Intervention for Pediatricians (2008): <http://pediatrics.aappublications.org/content/122/6/1387.full> and Oral Health Risk Assessment Timing and Establishment of the Dental Home (2009): <http://pediatrics.aappublications.org/content/111/5/1113.full>. Additional information from the policies regarding fluoride supplementation and fluoride varnish has been added to the footnote.

New references were added for several footnotes, also with no change to recommendations in the Periodicity Schedule:

- Footnote 5- Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report (2007): http://pediatrics.aappublications.org/content/120/Supplement_4/S164.full
- Footnote 13- Use of Chaperones During the Physical Examination of the Pediatric Patient (2011): <http://pediatrics.aappublications.org/content/127/5/991.full>
- Footnote 15- The Recommended Uniform Newborn Screening Panel (<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf>), as determined by The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, and state newborn screening laws/regulations (<http://genes-r-us.uthscsa.edu/sites/genes-r-us/files/nbsdisorders.pdf>), establish the criteria for and coverage of newborn screening procedures and programs. Follow-up must be provided, as appropriate, by the pediatrician.

For consistency, the title of "Tuberculin Test" has been changed to "Tuberculosis Testing." The title of "Newborn Metabolic/Hemoglobin Screening" has been changed to "Newborn Blood Screening."

AAP Principles Concerning Retail-Based Clinics

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- *Policy Statement*

POLICY STATEMENT

AAP Principles Concerning Retail-Based Clinics

abstract

FREE

The American Academy of Pediatrics views retail-based clinics (RBCs) as an inappropriate source of primary care for pediatric patients, as they fragment medical care and are detrimental to the medical home concept of longitudinal and coordinated care. This statement updates the original 2006 American Academy of Pediatrics statement on RBCs, which flatly opposed these sites as appropriate for pediatric care, discussing the shift in RBC focus and comparing attributes of RBCs with those of the pediatric medical home. *Pediatrics* 2014;133:e794–e797

INTRODUCTION

In 2006, the American Academy of Pediatrics (AAP) published its original policy statement opposing retail-based clinics (RBCs) as an appropriate source of medical care for infants, children, and adolescents and strongly discouraged their use.¹ This stance was based on the AAP commitment to the medical home model and its attributes of accessible, comprehensive, continuous, coordinated, compassionate, and culturally effective care for which the pediatrician and family share responsibility.² The structure and function of the RBC is not driven by the medical home model. The concerns expressed were based on the following attributes that influence the health care received by infants, children, and adolescents in RBCs:

- Fragmentation of care
- Possible decreased quality of care
- Provision of episodic care to children who have special needs and chronic diseases, who may not be readily identified
- Lack of access to and maintenance of a complete, accessible, central health record that contains all pertinent patient information
- Use of tests for the purpose of diagnosis without proper follow-up
- Possible public health issues that could occur when patients who have infectious diseases are in a commercial, retail environment with little or no isolation (eg, fevers, rashes, mumps, measles, strep throat)
- Seeing children who have “minor conditions,” as will often be the case in an RBC, is misleading and problematic. Many pediatricians use the opportunity of seeing the child for something minor to address other issues in the family, discuss any problems with obesity or mental health, catch up on immunizations, identify

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KEY WORDS

retail-based clinic, medical home, coordinated care

ABBREVIATIONS

AAP—American Academy of Pediatrics

RBC—retail-based clinic

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The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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undetected illness, and continue strengthening the relationship with the child and family. Visits for acute illnesses are important and provide an opportunity to work with patients and families to deal with a variety of other issues.

In expressing its opposition to RBCs in 2006, the AAP recognized that shifting economic and organizational dynamics of the health care system would likely support the continued existence and expansion of RBCs.¹ It outlined principles to which RBCs should be subject because of concern regarding the medical care received by pediatric patients in these settings. These principles included supporting the medical home model by referring patients back to their primary care physician or facilitating establishment of timely communication to the patient's pediatrician, using evidenced-based or evidence-informed medicine with requirements for oversight related to quality improvement, maintaining accepted protocols to manage infectious diseases, and opposing payment that offers financial incentives for use of RBCs by pediatric patients for the stated reason that the medical home is the optimal standard of care. This policy does not cover freestanding urgent care clinics, which are addressed in a separate AAP policy statement.

GROWTH, ACCEPTANCE, AND DIRECTION OF RBCs

Since the original RBC opened in 2000 in the St Paul/Minneapolis area, it is estimated that the number of RBCs has grown to more than 6000 as of 2012.^{2,3} Polls indicated that 15% of children were likely to use an RBC in the future, although the majority of patients seen in RBCs are adults.² These clinics generally follow a model of staffing by adult medicine or family practice-trained physician assistants or nurse

practitioners with off-site supervision by physician medical directors.^{4–6} Protocols are followed that dictate conditions and patients who can be seen as well as suggested treatment regimens to be followed.⁷ RBC protocols often restrict pediatric ages and conditions that will be seen by the providers. National organizations for member RBCs provide guidelines for accrediting and patient care.^{4,6}

Patients cite convenience as the most important reason for using RBCs.^{8–10} No appointment time is needed, and wait time is often minimal. Charges for minor illnesses treated are often less than a physician office and much less than an emergency department.^{11,12} Many RBCs bill insurance carriers, and some are able to bill Medicaid.⁸ Data on outcomes specifically looking at pediatric patients are limited, but minor illnesses, such as acute pharyngitis, demonstrate no significant issues with early return visits to primary care physicians.^{7,12,13}

RBCs are located in retail stores, such as grocery stores, drug stores, or “big box” stores. Average driving time for patients is less than 5 minutes, and average income and education for communities with RBCs are above average nationwide.^{5,14} More than 70% of patients report having a primary care physician. Demographic data to date do not indicate that expansion of RBCs has improved access to care in areas shown to have a shortage of primary care physicians.¹⁵

Most RBCs are owned by for-profit companies, many with a national presence.¹⁴ Most RBCs are not profitable as standalone entities and rely on location within a retail store for financial support. Some large companies have indicated plans to aggressively add RBCs to their stores and possibly expand their scope of services. Hospital and health care systems are increasingly partnering with or establishing their own RBCs

to capture or increase market share and provide other avenues of accessibility for their patients because of increasing shortages of primary care physicians in their networks and service areas.^{14,16} Insurance companies have also started expanding into opening their own full primary care centers with referral arrangements to specialists for identified problems.¹⁷

Many RBCs have protocols in place to refer patients who do not have primary care physicians or medical homes to a physician and provide correspondence of the patient's visit to those who have identified a primary care physician.

PEDIATRIC MEDICAL HOME VERSUS RBCs

A commentary published in *Pediatrics* in 2007 stressed that the emergence of RBCs has created a conflict between relative priorities of continuity of care and those of convenience and cost.¹⁸ Continuity of care embraces 3 primary dimensions: time, accessibility, and setting. Fostering a setting in which a pediatrician cares for a patient over many years (time) with knowledge of not only the medical but developmental and emotional needs of a patient and family significantly affect care and outcomes in a positive manner. Accessibility refers to ensuring care by a pediatrician and team with 24/7 availability for prompt and expert care in an appropriate medical setting. The setting is the pediatric medical home, which involves effective coordination of care throughout various medical settings, including office, hospital, home, school, and specialty referrals. The AAP, American Academy of Family Physicians, American College of Physicians, and American Osteopathic Association in 2007 issued a statement, “Joint Principles of the Patient-Centered Medical Home.” Summarized, the principles state¹⁸:

1. The patient should have an ongoing relationship with a personal physician trained to provide first contact, continuous, and comprehensive care;
2. The personal physician should lead a team of professionals who collectively take responsibility for the ongoing care of the patient;
3. The personal physician should be responsible for all aspects of the patient's care;
4. Care should be coordinated and integrated across all elements of the complex health care system; and
5. Care should be facilitated through registries, information technology, and health information exchange.

RBCs caring for children challenge this medical home concept by offering care that is arguably more convenient and less expensive but also fragmented, episodic, and not coordinated. RBC clinical providers lack pediatric training equivalent to pediatricians and do not provide after-hours coverage for patient/family questions or complications. RBCs do not typically contribute toward caring for children who cannot pay or live in underserved areas.¹⁵ As pediatric patients and their health issues become more complex, the concern exists that even a child presenting with a simple complaint may have a more serious unrecognized condition.¹⁹ In addition, there has been scope of care “creep” within the RBC setting, as these clinics now provide services such as childhood immunizations and “school and sports physicals.” These offerings impinge on core preventive care services of the pediatric medical home and are misperceived by patients and families as an appropriate substitute for regular preventive care within the medical home.

In an era of stagnant or decreasing physician payment rates by govern-

ment and private payer sources, one of the primary challenges for the primary care pediatrician is to continue to adhere to the central tenets of the medical home model by providing high-quality coordinated care in appropriate settings that optimize access, outcomes, and value. However, health care consumers, including those seeking pediatric health care services, also value convenience, a concept that, although similar, is not identical to access. Opportunities to improve convenience can include but are not limited to extended hours, open scheduling, and same-day appointments for even “minor” acute illness. Pediatricians will then have the opportunity to not only improve patient satisfaction but also increase office revenue and make the RBC setting less attractive for the care of children. At the same time, for many smaller pediatric practices, convenience can be a difficult or impossible metric with which to directly compete with RBCs without significant financial or work/life balance costs. Depending on the situation, the pediatric medical home may deem it prudent for access to incidental acute care to actively engage with RBCs within the local community as a means of expanding access without compromising the viability of the medical home and still provide an organizational plan for comprehensive care.

RECOMMENDATIONS REGARDING RBCs

1. RBCs Are an Inappropriate Source of Primary Care for Pediatric Patients

The AAP continues to oppose RBCs as a source of primary care for pediatric patients, because they risk increasing care that is fragmented and detrimental to the medical home concept of longitudinal and coordinated care.

2. Financial Payment

The AAP is opposed to payers offering lower copays or financial incentives for patients to receive care at RBCs in lieu of their pediatrician or primary care physician. Furthermore, the AAP strongly believes that the medical home is the optimal standard of care and that RBCs do not satisfy that definition. Payment for care received within the medical home must be continually evaluated to ensure that pediatricians and other primary care physicians receive adequate compensation for the continuous, coordinated, and comprehensive health care that they provide.

3. Support the Pediatric Medical Home

If pediatricians and the pediatric medical home wish to or need to use the services of an RBC within their community as a means to expand access for acute care outside of the medical home, both the medical home and the RBC should develop a formal collaborative relationship, which should include, but not be limited to:

- use of evidenced-based pediatric protocols and standards;
- pediatric quality review;
- prompt communication with the pediatric medical home of pertinent information for all visits of patients to RBCs;
- referral of all patients back to their pediatric medical home or arrangements to establish one for those who do not have one; and
- formal arrangements for after-hours coverage or emergency situations that may occur during a patient visit to an RBC.

CONCLUSIONS

The AAP continues to oppose RBCs as a source of primary care for pediatric patients. As the RBC model continues

to evolve, traditional RBCs, health systems, and insurance companies alike must recognize the critical role of the medical home in providing optimal health care for children. The AAP, its members, and the pediatric medical home should be the required partner for all RBCs that provide treatment of pediatric patients, with the pediatric medical home as the model of pediatric care.

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Adolescent Pregnancy: Current Trends and Issues— Addendum

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- *Policy Statement*

POLICY STATEMENT

Addendum—Adolescent Pregnancy: Current Trends and Issues

INTRODUCTION

The purpose of this addendum is to update pediatricians and other professionals on recent research and data regarding adolescent sexuality, contraceptive use, and childbearing since publication of the original 2005 clinical report, "Adolescent Pregnancy: Current Trends and Issues."¹ There has been a trend of decreasing sexual activity and teen births and pregnancies since 1991, except between the years of 2005 and 2007, when there was a 5% increase in birth rates. Currently, teen birth rates in the United States are at a record low secondary to increased use of contraception at first intercourse and use of dual methods of condoms and hormonal contraception among sexually active teenagers.² Despite these data, the United States continues to lead other industrialized countries in having unacceptably high rates of adolescent pregnancy, with over 700 000 pregnancies per year, the direct health consequence of unprotected intercourse.³ Importantly, the 2006–2010 National Survey of Family Growth (NSFG) revealed that less than one-third of 15- to 19-year-old female subjects consistently used contraceptive methods at last intercourse.⁴

TRENDS IN ADOLESCENT CHILDBEARING TRENDS

Most pregnancies among adolescents in the United States are unintended (unwanted or mis-timed). In fact, 88% of births to teenagers 15 to 17 years of age were the result of unintended pregnancies.⁵ Births to 15- to 19-year-old female subjects peaked in 1991 at 61.8 per 1000 female subjects; subsequently, the rate decreased annually, except for a slight increase in 2005–2007, to reach its nadir at 39.1 per 1000 female subjects in 2011.⁶ Birth rate statistics are not the same as pregnancy rate statistics. Birth rate statistics underestimate actual adolescent pregnancy rates. The birth rate numerator includes the number of actual births per 1000 individuals in that age group, but the pregnancy rate includes actual births, abortions, and best estimates of fetal loss per 1000 adolescents in that age group.⁷

The abortion rate among adolescents 15 to 19 years of age was 14.3 per 1000 female subjects and accounted for 16.2% of all abortions in 2008.⁸ During the decade 1999 to 2008, the abortion rate decreased by 20.7% among adolescents 15 to 19 years of age, with a 5.8% decrease noted from 2004 to 2008.

COMMITTEE ON ADOLESCENCE

KEY WORDS

adolescent health/medicine, teen pregnancy

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SEXUAL ACTIVITY AMONG ADOLESCENTS IN THE UNITED STATES

In the 2011 Youth Risk Behavior Survey (YRBS), 47% of both female and male high school students reported “ever having had sexual intercourse.”⁹ Similar data are found in the 2006–2010 NSFG, in which the proportion of female subjects 15 to 19 years of age who ever had sexual intercourse continued to decline from 51% in 1988 to 43%.⁴ The proportion of male subjects who ever had sexual intercourse decreased from 60% to 42%.⁴ The decrease in adolescents who ever had sex was most notable in non-Hispanic black female subjects, declining from 60% to 46%, compared with Hispanic female subjects, in whom the proportion decreased from 46% to 42%. Rates of ever being sexually active among non-Hispanic black male subjects decreased from 81% to 58% and, among Hispanic male subjects, it decreased from 60% to 46%.

Most adolescents conveyed that they were “going steady” with whom they had their first sexual intercourse experience. This “going steady” relationship was reported among 70% of female subjects and 56% of male subjects. However, the earlier the age of sexual debut, the less likely the first sexual partner was a regular partner and more likely to be just a friend or someone they recently met.⁴ Furthermore, as documented in the 2002 NSFG, the majority of adolescent female subjects had a partner who was 1 to 3 years older, and those younger than 14 years were also more likely than those aged between 15 and 19 years to have partners who were 4 or more years older. This age disparity creates the potential for more non-consensual sexual encounters, increasing the risk of pregnancy and sexually transmitted diseases.¹⁰ Both the 2011 YRBS and the 2006–2010

NSFG reported that approximately one-third of adolescents (YRBS: 34% of females, 33% of males; NSFG: 31% of females, 28% of males) described having had sex with at least 1 person during the previous 3 months.^{4,9} Nearly 14% had 4 or more lifetime partners, increasing the risk of sexually transmitted diseases.^{5,9} The number of partners increases as the age at first intercourse declines.¹⁰

The 2011 YRBS data demonstrated that more 12th graders (51% female, 44% male) were sexually active than ninth graders (19% female, 24% male).⁹ Sexual activity is not always consensual, as indicated by YRBS data in which 8% of youth (11.8% of female subjects, 4.5% of male subjects) reported ever having been forced to have sexual intercourse. Unwanted first sexual encounters were reported in the NSFG among 11% of female subjects 18 to 24 years of age who had first intercourse before age 20 years.⁴ Teenagers who report first sex at 14 years of age and younger are more likely to report that it was nonvoluntary, compared with those who were aged 17 to 19 years at sexual debut.¹⁰ Unwanted encounters may include dating violence, stranger assaults, and intra-familial sexual abuse/incest. Screening for sexual violence and unwanted sexual encounters should occur during evaluation of all sexually active adolescents.

CONTRACEPTIVE USE AND EFFICACY AMONG ADOLESCENTS

It is not only the use of a contraceptive method but the type of method used that can significantly affect rates of unintended pregnancy. A study published in 2012 found that the failure rate for the short-acting methods of the contraceptive pill, patch, or ring was 4.55 per 100 participant-years compared with the long-acting reversible contraceptive methods of the implant or intrauterine device, which

had a failure rate of 0.27 per 100 participant-years.¹¹ This study also found an age differential in which women younger than 21 years were twice as likely to have an unintended pregnancy when using short-acting methods, while having the same pregnancy rates (as cited earlier) when using long-acting methods. Long-acting reversible contraception is an important contraceptive option for the adolescent that has the clear potential to reduce unintended pregnancies.

The 2006–2010 NSFG reported that only 78% of adolescent female subjects and 85% of adolescent male subjects 15 to 19 years of age used a contraceptive method for first sexual intercourse, and 86% of female subjects and 93% of male subjects used a method at last intercourse over the previous 3 months.⁴ These percentages are not significantly different compared with those from 2002. There was, however, an increase in condom use by male subjects at first intercourse as well as in dual contraceptive use (simultaneous use of condoms and hormonal contraceptives) at both first and last intercourse by female subjects.⁴

Although NSFG data revealed that the condom was the most common method used by adolescents, among 15- to 19-year-old female subjects, 56% used oral contraceptive pills, 20% used an injectable method (depot medroxy-progesterone acetate), 10% used the contraceptive patch, and 5% used the contraceptive ring. The much less reliable method of withdrawal was used by 57% of adolescent female subjects and was essentially unchanged from 2002 (55%). Emergency contraception use increased from 8% to 14% from 2002.

With respect to specific data on contraceptive use at last sexual intercourse, data from the 2006–2010 NSFG report revealed that only one-third of

15- to 19-year-old female subjects used oral contraceptive pills, 12% used other hormonal methods (depot medroxyprogesterone acetate, hormonal implant, contraceptive patch or ring, and emergency contraception), 52% used condoms, and 11% used other methods (withdrawal, sterilization, intrauterine device, female condom, diaphragm, cervical cap, spermicides [foam, jelly, cream, or suppository], sponge, or calendar/rhythm method).⁴ Similarly, the 2011 YRBS demonstrated that as few as 23% of currently sexually active female students were taking birth control pills at the time of their most recent sexual intercourse.⁹ Use of the birth control pill according to age and race/ethnicity ranged from 8% to 30% and was highest among white female subjects and 12th graders. The last time depot medroxyprogesterone acetate use was specifically reported as an individual category was in the 2009 YRBS, in which use was reported by 4% of high school female subjects, with the highest rate among black students.¹² Differential use according to race/ethnicity was also demonstrated in the 2006–2010 NSFG report, which showed that non-Hispanic black students were 3 times less likely to use oral contraceptive pills compared with non-Hispanic white students.⁴ Further information about contraception use among male subjects and gay, lesbian, bisexual, and transgender youth is available in other American Academy of Pediatrics publications.^{13,14}

Condoms

Condoms are still the most common contraceptive method used by adolescent female and male subjects according to both the YRBS and NSFG.^{4,9} Condom use remained essentially unchanged for 10th through 12th graders between 2007 and 2011 but decreased from 69% to 64% among ninth graders.⁴ Condom use at last sexual intercourse

was described by 61% of sexually active students, with a race/ethnicity breakdown of 63% of white, 62% of black, and 55% of Hispanic students. More white female (56%) students reported that their partners used condoms than Hispanic female (48.0%) students. The group with the highest rate of condom use (73%) was black male students.⁸ Similar data were found in the 2006–2010 NSFG.⁴

Pregnancy Risk Assessment Monitoring System Data

Recent data from the 2004–2008 Centers for Disease Control and Prevention (CDC) Pregnancy Risk Assessment Monitoring System describe rates of pre-pregnancy contraceptive use among 15- to 19-year-old adolescent female subjects who subsequently gave birth in 5 of 19 states that had specific data about contraceptive use.¹⁵ The findings revealed that approximately 50% of non-Hispanic white, Hispanic, and non-Hispanic black teenagers were not using contraception before becoming pregnant.

Reasons for not using contraception included not thinking they could get pregnant (31%), the partner refusing to use contraception (24%), and not being concerned about becoming pregnant (22%). All of these factors have huge implications to the pediatrician regarding the provision of anticipatory guidance and health education to adolescents in their practices.

Adolescent Pregnancy Prevention

A Cochrane Review containing 41 randomized controlled trials ranging from health education, counseling, skills-building, contraception, contraception education, and faith-based group or individual counseling (including abstinence promotion) was completed in 2009.¹⁶ It showed that a combination of educational and contraceptive

interventions lowered the rate of unintended pregnancy among adolescents. However, on the basis of this review, there was no conclusive evidence that any specific intervention program had effects on initiation of sexual intercourse, use of birth control methods, or abortion.

In fiscal year 2010 appropriations, Congress funded the President's new Teen Pregnancy Prevention Initiative. Of the funds made available, \$75 million funded the replication of medically accurate and age-appropriate programs that reduce teen pregnancy, and \$25 million was allocated to develop and test additional models and innovative strategies.¹⁵ As part of this effort, the CDC is supporting a 5-year (2010–2015) multicomponent demonstration project to reduce the rates of pregnancies and births to youth by 10% in targeted communities. These demonstration projects are designed to increase linkage between teen pregnancy prevention programs and community-based clinical services, increase youth access to teen pregnancy prevention programs that are evidence based and/or evidence informed, and educate stakeholders about relevant evidence-based and evidence-informed strategies to reduce teen pregnancy. The needs and resources in the targeted communities are also identified.¹⁷

CONCLUSIONS

Although there are decreasing numbers of teenagers who become pregnant, the issue remains an important concern, particularly because the United States still has among the highest teen pregnancy rates in the industrialized world. Fortunately, there are many tools available to combat teen pregnancy, and the CDC effort is one example of renewed interest and distribution of resources for this important issue.

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Anterior Cruciate Ligament Injuries: Diagnosis, Treatment, and Prevention

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- *Clinical Report*

CLINICAL REPORT

Anterior Cruciate Ligament Injuries: Diagnosis, Treatment, and Prevention

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KEY WORDS

knee injuries, athletes, sports, adolescents

ABBREVIATIONS

ACL—anterior cruciate ligament

CI—confidence interval

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abstract

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The number of anterior cruciate ligament (ACL) injuries reported in athletes younger than 18 years has increased over the past 2 decades. Reasons for the increasing ACL injury rate include the growing number of children and adolescents participating in organized sports, intensive sports training at an earlier age, and greater rate of diagnosis because of increased awareness and greater use of advanced medical imaging. ACL injury rates are low in young children and increase sharply during puberty, especially for girls, who have higher rates of noncontact ACL injuries than boys do in similar sports. Intrinsic risk factors for ACL injury include higher BMI, subtalar joint overpronation, generalized ligamentous laxity, and decreased neuromuscular control of knee motion. ACL injuries often require surgery and/or many months of rehabilitation and substantial time lost from school and sports participation. Unfortunately, regardless of treatment, athletes with ACL injuries are up to 10 times more likely to develop degenerative arthritis of the knee. Safe and effective surgical techniques for children and adolescents continue to evolve. Neuromuscular training can reduce risk of ACL injury in adolescent girls. This report outlines the current state of knowledge on epidemiology, diagnosis, treatment, and prevention of ACL injuries in children and adolescents. *Pediatrics* 2014;133:e1437–e1450

INTRODUCTION

Anterior cruciate ligament (ACL) injuries are a serious concern for physically active children and adolescents. The ACL is 1 of the 4 major ligaments that stabilize the knee joint (Fig 1). Its main function is to prevent the tibia from sliding forward relative to the femur. The ACL also assists with preventing excessive knee extension, knee varus and valgus movements, and tibial rotation.^{1,2} An intact ACL protects the menisci from shearing forces that occur during athletic maneuvers, such as landing from a jump, pivoting, or decelerating from a run.

Physicians caring for young athletes have noted an increase in the numbers of ACL injuries over the past 2 decades.^{3,4} Reasons for the increase in ACL injury rate include the growing number of children and adolescents participating in organized sports, increased participation in high-demand sports at an earlier age, and a greater rate of diagnosis as a result of increased awareness that ACL injuries can occur in skeletally immature patients and more frequent use of advanced medical imaging.^{4–8}

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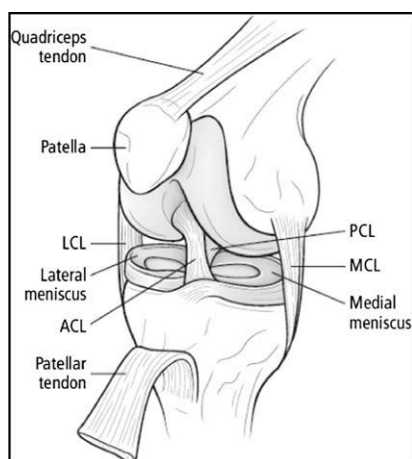


FIGURE 1

Anatomic structures of the knee. LCL, lateral collateral ligament; MCL, medial collateral ligament; PCL, posterior cruciate ligament. (Reproduced with permission from Harris SS, Anderson SJ, eds. *Care of the Young Athlete*. 2nd ed. Elk Grove Village, IL: American Academy of Pediatrics and American Academy of Orthopedic Surgeons; 2009:410.)

EPIDEMIOLOGY OF ACL INJURY

The incidence of ACL injuries in the general population can be estimated from national registries, which were established in Norway (2004), Denmark (2005), and Sweden (2006) to monitor the outcomes of ACL reconstruction surgery. Between 2006 and 2009, all Norwegian hospitals participated in the registry, with a total compliance of 97%. In the 10- to 19-year age group, the annual incidence of primary ACL reconstructions was 76 per 100 000 girls and 47 per 100 000 boys.⁹ This number underestimates the true incidence of ACL injuries, however, because it does not include those treated nonoperatively.

Most ACL injuries are sports-related; therefore, injury rates are higher in athletes. The National Collegiate Athletic Association Injury Surveillance System has compiled data for 16 sports (8 men's and 8 women's) over 16 years from a sample of colleges and universities (approximately 15%).² ACL injury rates were highest in men's spring football and women's gymnastics (33

per 100 000 athlete-exposures) (Fig 2). In women's sports, ACL injury rates represented a larger proportion of total injuries than in men's sports (3.1% vs 1.9%), with women's basketball and women's gymnastics topping the list at 4.9% of total injuries.¹⁰

Overall, high school athletes have lower rates of ACL injuries than do collegiate athletes (5.5 vs 15 per 100 000 athlete-exposures) but a similar injury distribution across sports.^{2,11} Since 2005, the National High School Sports-Related Injury Surveillance Study has compiled data on the incidence of ACL injuries in 18 sports.¹¹ From 2007 to 2012, ACL injury rates were highest in girls' soccer and boys' football (11.7 and 11.4 per 100 000 athlete-exposures, respectively) (Fig 3).

No well-designed epidemiologic studies to document ACL injury rates have been conducted in children younger than 14 years. Although there have been reports of sport-related ACL injuries in children as young as 5 years, the limited data available suggest that ACL disruptions in children younger than 12 years are rare.^{12–16} McCarroll et al¹⁶ found that of the 1722 ACL injuries diagnosed over

a 6-year period at their sports medicine center, 57 (3%) were in children 14 years and younger. The Norwegian ACL Surgical Registry collects data for all ACL surgeries performed at participating institutions nationwide. From 2004 to 2011, this registry recorded a total of only 8 to 9 ACL surgeries each year for children 11 to 13 years of age. This represents a small fraction (0.6%) of the total number of ACL surgeries recorded each year (1441) in this registry across all age groups. For the children who had surgery, the age at the time of injury ranged from 9 to 13 years.

The ACL surgery rate for 12- to 13-year-olds (3.5 per 100 000 citizens) was substantially lower than that for 16- to 39-year-olds (85 surgeries per 100 000 citizens), the age group at highest risk.⁹ Again, these numbers underestimate the actual injury rates, because they do not account for those treated nonoperatively.

Gender Differences

ACL injury risk begins to increase significantly at 12 to 13 years of age in girls and at 14 to 15 years of age in boys.^{9,12} Female athletes between 15 and 20

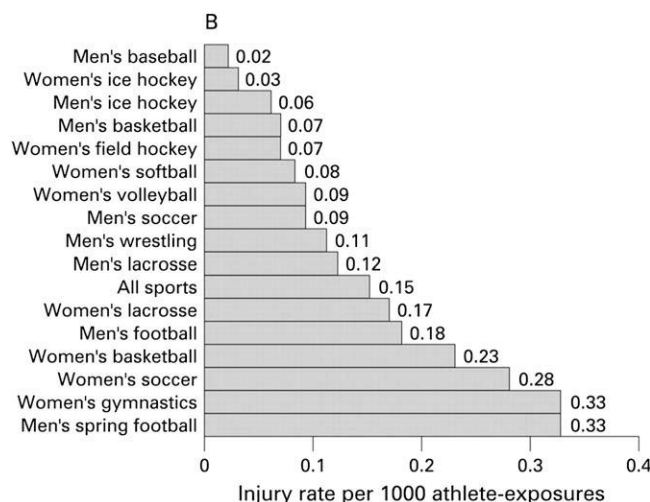


FIGURE 2

Collegiate ACL injury rates per 1000 athlete-exposures by sport. (Reproduced with permission from Renstrom P, Ljungqvist A, Arendt E, et al. Non-contact ACL injuries in female athletes: an international Olympic committee current concepts statement. *Br J Sports Med*. 2008;42(6):395.¹⁰)

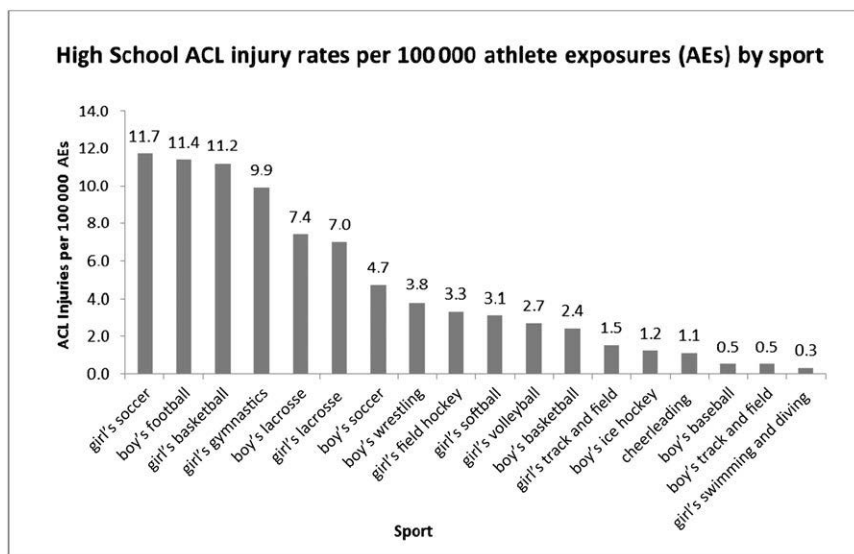


FIGURE 3

High School ACL injury rates per 100 000 athlete exposures (AEs) by sport. (Data from the National High School Sports-Related Injury Surveillance Study, 2007–08 to 2011–12 school years. Reproduced with permission from Comstock R, Collins C, McIlvain N. National High-School Sports-Related Injury Surveillance Study, 2009–2010 School Year Summary. Columbus, OH: The Research Institute at Nationwide Children's Hospital; 2010. Available at: <http://www.nationwidechildrens.org/cirp-ris-study-reports>.¹¹)

years of age account for the largest numbers of ACL injuries reported (Fig 4). The gender disparity in ACL injury rates among athletes begins to appear around the time of the growth spurt (12–14 years of age for girls and 14–16 years of age for boys), peaks during adolescence, then declines in early adulthood.^{10,12} At the high school level, ACL injury rates in gender-comparable sports (soccer, basketball, baseball/softball, track, volleyball) are

2.5 to 6.2 times higher in girls compared with boys.^{10,11,17} In college athletics, ACL injury rates are 2.4 to 4.1 times higher for women, and at the professional level, ACL injury rates for men and women are essentially equal.^{4,10,18} In high school sports, ACL injuries represent a higher proportion of all injuries in female versus male athletes (4.6% vs 2.5%), with girls' basketball topping the list (6%), followed by girls' soccer, girls' gymnastics, and girls'

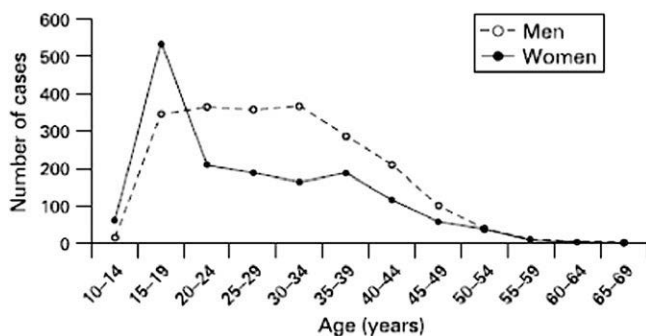


FIGURE 4

Distribution of patients in the Norwegian National Knee Ligament Registry by age and gender.^a (Reproduced with permission from Renstrom P, Ljungqvist A, Arendt E, et al. Non-contact ACL injuries in female athletes: an international Olympic committee current concepts statement. *Br J Sports Med*. 2008;42(6):395.¹⁰) ^aNumber of cases (y-axis) indicates number of ACL reconstructions.

volleyball (each 5%). Compared with boys, girls are more likely to have surgery and less likely to return to sports after an ACL injury.^{17,19} Among female high school basketball players, knee injuries were the most common cause of permanent disability, accounting for up to 91% of season-ending injuries and 94% of injuries requiring surgery.^{20,21}

CONSEQUENCES OF ACL INJURY

An ACL injury at an early age is a life-changing event. In addition to surgery and many months of rehabilitation, the treatment costs can be substantial (\$17 000–\$25 000 per injury), and the time lost from school and sports participation can have considerable effects on the athlete's mental health and academic performance.^{22,23} Although ACL injuries account for approximately 3% of all injuries in college sports, they account for 88% of injuries associated with 10 or more days of time lost from sports participation. Freedman et al²⁴ examined the academic transcripts of college students who underwent ACL reconstruction surgery. Compared with an age-matched control group, those who had surgery had a significant drop in grade point average of 0.3 points during the semester of injury ($P = .04$). Similarly, Trentacosta et al²⁵ found that athletes 18 years and younger who had ACL reconstruction surgery during the school year reported that it had a negative effect on their grades.

Beyond these more immediate effects, an ACL injury also has long-term health consequences. Regardless of the type of treatment, athletes with ACL injury are up to 10 times more likely to develop early-onset degenerative knee osteoarthritis, a condition that not only limits one's ability to participate in sports but also often leads to chronic pain and disability.^{26,27} A systematic review of a series of long-term studies suggests the rates of degenerative

knee osteoarthritis 10 to 20 years after ACL injury are more than 50%.²⁷ This means children and teenagers who suffer ACL injuries are likely to face chronic pain and functional limitations from knee osteoarthritis in their 20s and 30s. None of these studies, however, demonstrated that ACL reconstruction lowered the risk for osteoarthritis. In fact, one 5-year prospective study showed that patients who had ACL reconstruction had a higher level of knee arthrosis on radiographs and bone scans, compared with patients who did not undergo ACL reconstruction.²⁸

INJURY MECHANISMS

The mechanism of ACL injuries in athletes is likely multifactorial. Proposed theories to explain the mechanisms underlying ACL injury include extrinsic (physical and visual perturbations, bracing, and shoe-surface interaction) and intrinsic (anatomic, hormonal, neuromuscular, and biomechanical) variables. Identification of extrinsic and intrinsic risk factors associated with the ACL injury mechanism provides direction for targeted interventions to high-risk individuals.

At least 70% of ACL injuries are non-contact in nature^{29,30}; however, the specific definition of a noncontact ACL injury varies from study to study. Some define a noncontact ACL injury as one that occurs in the absence of a player-to-player (body-to-body) contact. Others define noncontact ACL injury as one that occurs in the absence of a direct blow to the knee. An ACL injury resulting from body-to-body contact but with no direct blow to the knee may be classified as “noncontact ACL injury with perturbation.”

Video analysis of ACL injury during competitive sports play indicates a common body position associated with noncontact ACL injury (Fig 5) in which (1) the hip is internally rotated,

(2) the knee is close to full extension, (3) the foot is planted, and (4) the body is decelerating, leading to apparent valgus collapse of the knee or “dynamic knee valgus.”^{31–33} ACL injury is also observed to occur when the body's center of mass is behind and away from the base of support or the area of foot-to-ground contact.³¹

RISK FACTORS

ACL injury risk in young athletes is likely multifactorial. Injury data from many fields demonstrate that numerous physical and psychological parameters affect ACL injury rates.

Genetics

Genetic factors likely play a role, although the genetic underpinnings of increased ACL injury risk have only recently begun to be examined.³⁴

Hormones

Hormonal factors also likely play a role; however, results of studies investigating hormonal factors are both equivocal and controversial.³⁵ Although the female knee appears to get slightly more lax, on the order of 0.5 mm, at midmenstrual cycle, injuries tend to cluster near the start of menses at the polar opposite time in the cycle.^{36,37}

Previous Injury

Similar to other musculoskeletal injuries, one of the single best predictors of future ACL injury is previous ACL injury. One study found the incidence rate of ACL injury in athletes who have had ACL reconstruction was 15 times greater than that of control subjects.³⁸ Female athletes were 4 times more likely to suffer a second ACL injury in either knee and 6 times



FIGURE 5

Dynamic knee valgus: hips are internally rotated and adducted, tibiae are externally rotated, and feet are everted.

more likely to suffer a new ACL injury in the contralateral knee than male athletes. In fact, subsequent injuries to the contralateral ACL are twice as common as reinjury of the reconstructed ACL (11.8% vs 5.8%).³⁹ Genetic, anatomic, and neuromuscular factors likely play a role.

Age and Gender

Although ACL injury rates increase with age in both genders, girls have higher rates immediately after the growth spurt.^{9–12,16} It is likely that the increases in body weight, height, and bone length during pubertal development underlie the mechanism of increased risk of ACL injury with increasing age. During puberty, the tibia and femur grow at a rapid rate.⁴⁰ This growth of the 2 longest levers in the human body translates into greater torques on the knee.⁴¹ Increasing height leads to a higher center of mass, making muscular control of this center of mass more challenging. Increasing body weight is associated with greater joint force that is more difficult to balance and dampen during high-velocity athletic movements. In pubertal boys, testosterone mediates significant increases in muscular power, strength, and coordination, which affords them with greater neuromuscular control of these larger body dimensions. Pubertal girls do not experience this same growth spurt in muscular power, strength, and coordination, which likely explains their higher rates of ACL injuries compared with pubertal boys.⁴¹ That preadolescent athletes show no gender differences in ACL injury rates further supports this theory.¹²

Anatomic/Anthropometric Factors

Greater weight and BMI have been associated with increased risk of ACL injury.^{31,42} A study of military recruits found that body weight or BMI >1 SD above the mean was associated with

a 3.2 and 3.5 times greater risk of ACL injury, respectively.⁴² In a study of female soccer players older than 8 years, BMI was a significant risk factor for knee injury.³¹

An increased quadriceps angle (Q angle) has been postulated as a risk factor, but there have been no prospective clinical studies to investigate the relationship between Q angle and ACL injury risk.^{43–45} A narrow intercondylar notch, where the ACL is housed, is proposed to increase ACL injury risk, because a narrow notch tends to be associated with a smaller, weaker ACL and also could cause increased elongation of the ACL under high tension.^{46,47} Some studies have shown that a narrow notch increases risk of ACL injury^{42,47,48}; however, others have shown no association between notch width and ACL injury.^{18,49,50} Subtalar joint overpronation has been associated with noncontact ACL injuries,⁵¹ likely because overpronation increases anterior translation of the tibia with respect to the femur, thereby increasing the strain on the ACL.⁵²

Generalized joint laxity and knee hyperextension were found to significantly increase the risk for ACL injury in female soccer players.⁵³ Patients with ACL injury have significantly more knee recurvatum at 10 and 90 degrees of hip flexion and an increased ability to touch palms to floor.²⁹ Athletes with generalized joint laxity had a 2.7 times greater risk of ACL injury than did those without generalized laxity, and those with increased anterior-posterior laxity of the knee, as measured by a knee arthrometer, had an approximately 3 times greater risk of ACL injury than did those without such laxity.⁴² Joint laxity affects not only sagittal knee motion (hyperextension) but also coronal knee motion (valgus), which can strain the ACL and be related to increased risk in athletes.^{29,42,54}

Neuromuscular Factors

Muscle strength and coordination have a direct effect on the mechanical loading of the ACL during sport movements.^{55,56} Poor neuromuscular control of the hip and knee and postural stability deficits have been shown to be risk factors for ACL injury.^{54,57} Landing and pivoting sports involve a great deal of rapid deceleration and acceleration movements that push and pull the tibia anteriorly and place the ACL under stress. This tibial translation can be modulated by hamstrings and quadriceps activity.^{58,59} In vivo studies show when subjects were asked to contract their muscles, knee laxity is reduced by 50% to 75%.⁵⁸ Activation of the quadriceps before the hamstrings, a pattern more frequently seen in female individuals, increases the anterior shear force that directly loads the ACL and also could be related to increased dynamic valgus alignment at initial contact during cutting and landing maneuvers.^{41,60–65} Although fatigue is often cited as a potential risk factor for ACL injury, there are relatively few published studies to support or refute this.⁶⁶

MAKING THE DIAGNOSIS

History

The patient with an acute ACL tear typically presents with pain, a knee effusion, a reduction in knee motion, and difficulty bearing weight. Often a “pop” is heard or felt by the athlete at the time of injury. The prevalence of an ACL tear in a pediatric athlete with a traumatic knee hemarthrosis is about 65%.⁶⁷ The patient with a chronic ACL tear typically presents with recurrent effusions and the sense that the knee “gives way” or is unstable with attempts at cutting, twisting, or jumping sports.

Physical Examination

In a pediatric athlete with an acute traumatic knee effusion, the Lachman test, anterior drawer test, and pivot

shift test are clinical examinations that aid in making the diagnosis of an ACL tear.

The Lachman test is performed with the patient supine (Fig 6). The injured knee is flexed to 30 degrees. The examiner places 1 hand behind the tibia with the examiner's thumb on the tibial tubercle and the other hand on the patient's lower thigh. The tibia is pulled anteriorly. Examinations of both knees are compared. Increased anterior movement of the tibia relative to the femur without a firm end point compared with the examination of the uninjured knee suggests a torn ACL.

The anterior drawer test also is performed with the patient supine but with the knee flexed to 90 degrees (Fig 7). The examiner grasps the tibia just below the knee joint, with the examiner's thumbs placed on either side of the patellar tendon. The tibia is pulled forward. An increased amount of anterior tibial translation compared with the opposite leg or a lack of a firm end point suggests a torn ACL.⁶⁹ Both the Lachman and anterior drawer tests require a relaxed patient without hamstring guarding.

The pivot shift test is performed with the patient supine and the knee extended (Fig 8). The examiner stresses

the lateral side of the knee while gradually flexing the patient's knee. A "clunk" sensation occurs when the partly subluxated tibia relocates in relation to the femur, indicating that the ACL is torn. The pivot shift test is often difficult to perform in the pediatric athlete with an acute knee injury because of pain and guarding.

The Lachman test is considered the most accurate of the 3 commonly performed clinical tests for an acute ACL tear, showing a pooled sensitivity of 85% (95% confidence interval [CI] 83–87) and a pooled specificity of 94% (95% CI 92–95). The pivot shift test is very specific, namely 98% (95% CI 96–99), but has a poor sensitivity of 24% (95% CI 21–27).^{68,69} Last, the knee arthrometer is an objective, accurate, and validated tool that measures, in millimeters, the amount of tibial translation relative to the femur while performing a Lachman test and, thus, augments the clinical examination when examining a patient with an ACL tear.^{70,71}

Imaging

For the pediatric athlete who presents with a traumatic knee effusion, plain radiographs should be obtained to rule out fracture, dislocation, osteochondral

injury, or physeal injury in addition to, or instead of, an ACL tear. MRI is usually not necessary to make the diagnosis of an ACL tear, as a positive Lachman test result is sufficient. However, in the pediatric patient whose physical examination is difficult to perform because of pain, swelling, and/or lack of cooperation or if there is concern for associated injuries or subtle physeal fracture, MRI may be a valuable ancillary tool.^{72–76} MRI also can be useful for surgical planning. Sensitivity and specificity of MRI for detecting ACL tears in children has been reported to be 95% and 88%, respectively.⁷⁶ For meniscal tears in children, MRI has been reported to be 100% sensitive and 89% specific.⁷² One study found that the sensitivity, specificity, positive predictive value, and accuracy of MRI for identifying all categories of pathologic changes were lower for pediatric (ages 4–14 years) versus adolescent (ages 15–17 years) patients.⁷⁵

TREATMENT

The treatment of ACL tears in the pediatric athlete is challenging and controversial. An ACL tear in a child is not a surgical emergency. Multiple timely discussions with the parents and the child about the appropriate management options and understanding their goals and expectations are very important.⁷³ Surgery is not absolute. The general indications for surgery include the patient's inability to participate in his or her chosen sport, instability that affects activities of daily living, and an associated repairable meniscal tear or a knee injury with multiple torn ligaments. Treatment of ACL injuries in the skeletally immature patient remains controversial, because standard ACL reconstructions involve the use of drill holes that cross the open physes and may potentially cause growth disturbance, such as shortening or angulation of the child's leg.⁸ A meta-analysis of 55



FIGURE 6

Lachman test. (Reproduced with permission from Harris SS, Anderson SJ, eds. *Care of the Young Athlete*. 2nd ed. Elk Grove Village, IL: American Academy of Pediatrics and American Academy of Orthopedic Surgeons; 2009:413.)



FIGURE 7

Anterior drawer test. (Reproduced with permission from Sarwark JF, ed. *Essentials of Musculoskeletal Care*. 4th ed. Rosemont, IL: American Academy of Orthopedic Surgeons; 2010:638.)



FIGURE 8

Pivot shift test. (Reproduced with permission from Sarwark JF, ed. *Essentials of Musculoskeletal Care*. 4th ed. Rosemont, IL: American Academy of Orthopedic Surgeons; 2010:637.)

studies suggested that the risk of leg length difference or angular leg deviations was approximately 2% after ACL reconstruction in children and adolescents.⁷⁷ The authors recommended randomized controlled trials to clarify this risk more accurately. Ideally, surgical treatment of an ACL tear in a skeletally immature athlete would be postponed until skeletal maturity, and

the athlete would not develop meniscal tears during that waiting time. In the past, delay in surgical treatment was very common. Orthopedic surgeons recommended nonoperative treatment, including a brace, rehabilitation, and sports restriction for many months until skeletal maturity occurred and traditional ACL surgery could be performed safely.^{73,78,79} For some pediatric

athletes and parents, conservative management still may be a reasonable treatment option. However, many pediatric athletes and their parents are less inclined to agree to restrict the athlete's activity. In such cases, an ACL tear in the pediatric athlete treated conservatively can lead to additional instability episodes, meniscal tears, articular cartilage damage, and early-onset arthritis.^{80–84} Therefore, most recent literature now supports early surgery for pediatric athletes with an ACL-deficient knee and recurrent episodes of instability.^{82,85–87} Overall, ACL surgery is about 90% successful in restoring knee stability and patient satisfaction.⁸⁸

No consensus exists on the best method to treat an ACL tear in a pediatric athlete. Safe and effective surgical techniques continue to evolve.⁷⁸ However, the current literature suggests reasonable, evidenced-based management options that minimize the risks of iatrogenic growth plate injury.⁸⁹ For example, ACL surgery in a pediatric athlete is often performed via a physeal-sparing technique or a transphyseal technique.^{86,90–92} The physeal-sparing technique avoids injury to the growth plate, but it places the graft in a nonanatomic position. An accurate understanding of the athlete's physical maturity by determining skeletal age and Tanner stage helps to identify which treatment is best for a specific patient.^{73,86,87,92–98} The most common method of measuring the patient's skeletal age is to compare an anteroposterior radiograph of the patient's left hand and wrist to an age-specific radiograph in the Greulich and Pyle atlas.⁹⁴ Tanner stage can be determined by self-assessment, which has been shown to be valid and reliable.⁹⁹

Patients with open physes at Tanner stage III and skeletal age of less than 14 in girls and less than 16 in boys can be offered the option of activity modification, functional bracing, rehabilitation, and careful follow-up. Surgery is

indicated in skeletally immature patients with a torn ACL and an additional repairable meniscal injury and in patients who failed conservative care. In addition, ACL surgery can be elected by patients unwilling to comply with activity restrictions and bracing. Parents and patients who request surgery before maturation of the growth plates should be counseled about the risk of angular or longitudinal growth injury and the possible need for additional surgery.^{16,100–103}

Most orthopedic surgeons select a surgical treatment option based on the patient's skeletal and physiologic age. For example, in the high-risk, most skeletally immature athlete (skeletal age less than 11 in girls and less than 13 in boys, and Tanner stage I or II) an extraphyseal procedure using a band of the iliotibial tendon or a hamstring tendon graft passed over the top of the lateral femoral condyle and through a groove in the anterior tibia is a reasonable surgical option.^{15,103–106} Both of these extraphyseal procedures avoid the growth plate to prevent the risk of growth disturbance. A third option for the completely immature pediatric athlete is a more technically demanding all-epiphyseal procedure using hamstring tendon grafts. Some authors have used intraoperative 3-dimensional computed tomography to confirm the precise tunnel location and minimize risk of physeal injury.⁸⁹

In the intermediate-risk mid-age child (skeletal age 11 to 14 in girls and 13 to 16 in boys, and Tanner stage III or IV), the previous physeal-sparing methods may be selected; however, many of these intermediate-maturity patients are safely and more appropriately treated with transphyseal reconstruction using small 7- to 8-mm centrally placed drill holes and a soft tissue graft, such as the hamstring tendons or an allograft.^{106–109} Physeal injury can be minimized by us-

ing a small drill hole and soft tissue grafts and by placing the fixation away from the physis. Patients and parents should be counseled that there remains a small risk of physeal injury and a possibility of additional surgery for angular or growth disturbance.

Last, adolescents who are approaching skeletal maturity (skeletal age older than 14 in girls and older than 16 in boys, Tanner stage V) can undergo anatomic ACL surgery with tibial and femoral drill holes and the surgeon's graft of choice with minimal risk of physeal injury.^{82,110,111} Autografts and allografts are both reasonable graft choices depending on the patient and surgeon preferences. Autografts have a lower graft failure rate in 2 studies.^{112,113}

Rehabilitation after ACL surgery may need to be modified for the individual patient and the particular surgical procedure. In general, a graduated rehabilitation program emphasizing full extension; immediate weight bearing; active range of motion; and strengthening of the quadriceps, hamstrings, hip, and core can be started in the first few weeks after surgery. Progressive rehabilitation during the first 3 months after surgery includes range-of-motion exercises, patellar mobilization, proprioceptive exercises, endurance training, and closed-chain strengthening exercises. Straight-line jogging, plyometric exercises, and sport-specific exercises are added after 4 to 6 months. Return to play typically occurs 7 to 9 months after surgery.

Return to Sport

Studies of competitive athletes, most of whom were older than 18 years, in a variety of sports have demonstrated that 78% to 91% returned to sports participation after ACL reconstruction.¹¹⁴ However, only 44% to 62% returned to their previous level of athletic performance.^{114–119} Female athletes were less likely than male

athletes to return to sports after ACL injury or ACL reconstruction.^{19,119,120}

ACL INJURY PREVENTION

Bracing

It is unlikely that prophylactic bracing can decrease the risk of ACL injury. The relative effects of 6 different brace designs on anterior tibial translation and neuromuscular function were studied in chronically unstable ACL-deficient patients.¹²¹ Bracing decreased anterior tibial translation in the range of 30% to 40% without the stabilizing contractions of the hamstrings, quadriceps, or gastrocnemius muscles. With muscle activation and bracing, anterior tibial translation was decreased between 70% and 85%. However, the braces slowed hamstring muscle reaction times. A brace with a 5-degree extension stop decreased extension on landing.¹²²

Functional bracing after ACL reconstruction has been studied using randomized controlled cohorts placed into braced or nonbraced groups.¹²³ The braced group was instructed to wear a functional knee brace for all cutting, pivoting, or jumping activities for the first year after ACL reconstruction. There were no differences between groups in knee stability, functional testing, subjective knee scores, and range of motion or strength testing, and the investigators concluded that postoperative bracing did not change outcomes. Data are insufficient at this time to determine whether functional bracing decreases the risk of ACL injury or reinjury. Knee bracing does not improve functional performance of subjects after ACL reconstruction and may actually reduce running and turning speed.¹²⁴

Neuromuscular Training Programs

Although ACL injuries occur too quickly for reflexive muscular activation,

athletes can adopt or “preprogram” safer movement patterns that reduce injury risk during landing, pivoting, or unexpected loads or perturbations during sports movements.^{54,60} With sufficient neuromuscular control of knee position to avoid dynamic valgus, knee stability may be improved during competitive sport and the risk of ACL injury can be significantly reduced. A collection of prospective cohort studies and randomized controlled trials have examined the effect of neuromuscular training programs on ACL, knee, and other lower-extremity injuries in soccer, basketball, volleyball, and handball (Fig 9).^{22,125–137} Some studies used only 1 or 2 types of exercises, such as plyometric exercises and/or balance exercises, and others applied a more comprehensive approach by including plyometrics (repetitive jumping exercises designed to build lower-extremity strength and power), strengthening, stretching, and balance training.

Systematic examination of the data extracted from these studies leads to a few potentially valuable generalizations.^{138–140} Plyometric training combined with technique training and feedback to athletes regarding proper form were the common components of programs that effectively reduced ACL injury rates. Balance training alone may not be sufficient to reduce ACL injury risk. Although some of the effective programs did not include strength training, those that did were among the most effective at decreasing ACL injury rates. ACL injury reduction was greatest for soccer athletes, and combined pre- and in-season training was more effective than pre- or in-season training alone. With respect to age, the greatest reduction in injury risk was demonstrated for female athletes in their mid-teens (14–18 years) compared with those in their late teens (18–20 years) and adults (>20 years), with 72% risk reduction for those <18 years of age

and 16% risk reduction for those ≥18 years of age. This suggests the best window of opportunity for ACL injury risk reduction may be during early pubertal maturation, at or just before girls’ neuromuscular risk factors start to become evident and ACL injury rates in girls dramatically increase. It is unknown whether neuromuscular training or other interventions can modulate the increased risk of early-onset degenerative knee arthritis after ACL injury.¹⁴¹

More information about specific evidence-based neuromuscular training programs can be found in the respective articles describing their study results.^{125–137} In addition, the AAP has compiled a series of evidence-based resources that include instructional videos for pediatricians, athletes, and coaches who would like to learn more about neuromuscular training and how to perform the preventive exercises (<http://www.aap.org/cosmf>).

CONCLUSIONS AND GUIDANCE FOR CLINICIANS

1. The number of ACL injuries in young athletes has increased over the past 2 decades, coincident with the growing number of children and adolescents participating in or-

ganized sports, intensive sports training at an earlier age, and greater rate of diagnosis because of increased awareness and greater use of advanced medical imaging.

2. Intrinsic risk factors for ACL injury include higher BMI, subtalar joint overpronation, generalized ligamentous laxity, and decreased neuromuscular control of the trunk and lower extremities.
3. ACL injury rates are low in young children and increase sharply during puberty, especially for girls, who have higher rates of ACL injuries than boys do in similar sports.
4. Although there likely are multiple factors underlying the differences in noncontact ACL injury rates in male and female athletes, neuromuscular control may be the most important and most modifiable factor.
5. ACL injuries often require surgery and/or many months of rehabilitation and substantial time lost from school and sports participation.
6. The best physical examination test for an ACL tear is the Lachman test.
7. MRI can be valuable for diagnosing ACL tears and associated meniscal and chondral injury in

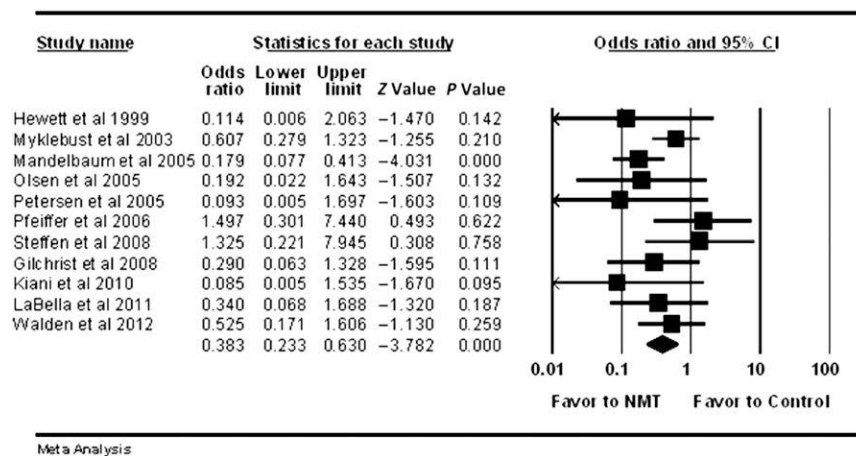


FIGURE 9

Reduction of noncontact ACL injury with neuromuscular training. (Reproduced with permission from Myer GD, Sugimoto D, Thomas S, Hewett TE. The influence of age on the effectiveness of neuromuscular training to reduce anterior cruciate ligament injury in female athletes: a meta-analysis. *Am J Sports Med*. 2013;41(1):209.¹³⁸)

the pediatric athlete whose physical examination is difficult to perform because of pain, swelling, and lack of cooperation.

8. An ACL tear in a youth athlete is not a surgical emergency. Multiple discussions with the athlete and parents may be needed to understand the athlete's goals and parental expectations and to educate the family about possible treatment options.
9. The patient's skeletal age, measured by an anteroposterior radiograph of the left hand and wrist, and Tanner stage are helpful for the physician in deciding the most appropriate treatment of an ACL tear in a skeletally immature athlete.
10. Pediatricians and orthopedic surgeons treating young people with ACL injuries should advise them that regardless of treatment choice, they are at increased risk of early-onset osteoarthritis in the injured knee. Such discussions should be appropriately documented in the patient's medical record.
11. Musculoskeletal changes that decrease dynamic joint stability in high-risk female athletes and potentially lead to higher injury rates in this population could be modified if neuromuscular training interventions are instituted in early-middle adolescence, when the neuromuscular risk factors for ACL injury start to develop.
12. Neuromuscular training appears to reduce the risk of injury in adoles-

cent female athletes by 72%. Prevention training that incorporates plyometric and strengthening exercises, combined with feedback to athletes on proper technique, appears to be most effective.

13. Pediatricians and orthopedic surgeons should direct patients at highest risk of ACL injuries (eg, adolescent female athletes, patients with previous ACL injury, generalized ligamentous laxity, or family history of ACL injury) to appropriate resources to reduce their injury risk (<http://www.aap.org/cosmf>). Such discussions also should be appropriately documented in the patient's medical record.
14. Pediatricians and orthopedic surgeons who work with schools and sports organizations are encouraged to educate athletes, parents, coaches, and sports administrators about the benefits of neuromuscular training in reducing ACL injuries and direct them to appropriate resources (<http://www.aap.org/cosmf>).

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Application of the Resource-Based Relative Value Scale System to Pediatrics

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- *Policy Statement*

POLICY STATEMENT

Application of the Resource-Based Relative Value Scale System to Pediatrics

abstract

FREE

The majority of public and private payers in the United States currently use the Medicare Resource-Based Relative Value Scale as the basis for physician payment. Many large group and academic practices have adopted this objective system of physician work to benchmark physician productivity, including using it, wholly or in part, to determine compensation. The Resource-Based Relative Value Scale survey instrument, used to value physician services, was designed primarily for procedural services, leading to current concerns that American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) surveys may undervalue nonprocedural evaluation and management services. The American Academy of Pediatrics is represented on the RUC, the committee charged with maintaining accurate physician work values across specialties and age groups. The Academy, working closely with other primary care and subspecialty societies, actively pursues a balanced RUC membership and a survey instrument that will ensure appropriate work relative value unit assignments, thereby allowing pediatricians to receive appropriate payment for their services relative to other services. *Pediatrics* 2014;133:1158–1162

BACKGROUND

Creation of Resource-Based Relative Value Scale Payment System

The Medicare Resource-Based Relative Value Scale (RBRVS) was legislated by the Omnibus Budget Reconciliation Act of 1989. The RBRVS-based physician payment system relies on¹ objective measures of physician work, termed work relative value units (wRVUs)²; assessments of the practice expense in providing professional services to patients; and³ the professional liability insurance expense inherent in each specific service. These 3 components are then corrected for geographic variations in salaries and the cost of goods and services. In this way, the RBRVS system has eliminated many of the dramatic disparities that existed when payments were based on the customary, prevailing, and reasonable fees for the service provided.

Conversion Factor

The RBRVS mandate was accompanied by a legislative requirement for annual Medicare budget neutrality. To accomplish this, Congress established the annually updated conversion factor (CF); the dollar

COMMITTEE ON CODING AND NOMENCLATURE

KEY WORDS

Resource-Based Relative Value Scale (RBRVS), medicare payment, RUC, CPT, valuation, physician work, coding

ABBREVIATIONS

AAP—American Academy of Pediatrics
 ACA—The Patient Protection and Affordable Care Act
 CF—conversion factor
 CMS—Centers for Medicare and Medicaid Services
 CPT—Current Procedural Terminology
 HCPCS—Healthcare Common Procedural Coding System
 HIPAA—Health Insurance Portability and Accountability Act of 1996
 ICD-9-CM—International Classification of Diseases, Ninth Revision, Clinical Modification
 ICD-10-CM—International Classification of Diseases, Tenth Revision, Clinical Modification
 NCCI—National Correct Coding Initiative
 RBRVS—Resource-Based Relative Value Scale
 RUC—American Medical Association/Specialty Society Relative Value Scale Update Committee
 RVU—relative value unit
 SGR—sustainable growth rate
 wRVU—work relative value unit

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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amount Medicare will pay for each relative value unit (RVU) of service (total RVU $\times$ CF = payment). By legislation, annual increases for new technology or treatments were restricted to \$20 million annually. Congress provided for an annual update to the CF based on the percentage increase in the Medicare Economic Index. This index is a comparison of the projected increases in use, described as the Medicare Volume Performance Standard, to the actual increase in spending and other Medicare funding factors. Inability to control this growth in physician services led to the Balanced Budget Act of 1997, which replaced the Medicare Volume Performance Standard with the sustainable growth rate (SGR) system now used to control Medicare expenditures.

Sustainable Growth Rate

The SGR is a complex formula used to determine the annual CF on the basis of the projected growth in per capita gross domestic product. Higher-than-projected use of services results in a reduction to the following year's CF. Expected reductions in the Medicare CF over previous years (eg, -20.1% for 2014) have only been avoided by last-minute congressional legislative action. The Patient Protection and Affordable Care Act (ACA) of 2010 replaces the unworkable SGR formula with one that is more closely tied to inflation and the Medicare Economic Index. The ACA also establishes a public/private committee to recommend the level of annual increase in CF. Recent bipartisan Congressional bills would replace the SGR but freeze Medicare payments for 10 years. The AAP strongly endorses this replacement but will also insist that this freeze not delay continued efforts to attain cognitive and non-face-to-face care parity with procedural services.

The American Academy of Pediatrics (AAP) supports the replacement of the

SGR formula with one that more closely ties physician payment to inflation and the medical economic index, similar to that proposed in the ACA.

Five-Year Review Process

At RBRVS's inception, Congress also mandated a 5-year review of work values to review changes in medical practice that might increase or decrease the cost of providing specific services or to revisit perceived inequities in RBRVS values. For example, as part of the 2010 5-year review, preventive medicine services codes were resurveyed on the basis of updated *Bright Futures* care recommendations, resulting in increased wRVUs for those services.

Pediatric Current Procedural Terminology Codes

The AAP Committee on Coding and Nomenclature has sought and continues to seek input from AAP sections, councils, and committees regarding the development of new/revised *Current Procedural Terminology* (CPT) codes that reflect changes in the provision of services to children. New CPT codes or revisions to existing CPT codes can be proposed by any individual or entity, but those sponsored by medical specialty societies are considered more representative of current medical practice. Once a new/revised CPT code is accepted by the CPT Editorial Panel, the AAP Committee on Coding and Nomenclature then works within the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) process to provide the Centers for Medicare and Medicaid Services (CMS) with wRVU and direct practice expense recommendations that accurately reflect the resources expended in providing those services to children. Each November, the CMS publishes (in the *Federal Register*) the upcoming year's RBRVS fee schedule for public

comment. In some cases, the CMS accepts the RUC recommended values. However, in other cases, the CMS has published values that have differed from those recommended by the RUC and, as such, the AAP has been very active in its advocacy efforts to reverse those CMS decisions when they have adversely affected payment for services that are critically important to children or recommended by established guidelines, such as those contained in *Bright Futures*.

Non-Medicare Use of RBRVS

Payers are required to use CPT as the procedural code set, as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The majority of non-Medicare payers, including state Medicaid programs and commercial insurers, use the Medicare RBRVS payment system to set payment for CPT codes. According to an American Medical Association (AMA) survey of 127 different public and private payers, 77% of respondents use the Medicare RBRVS.¹ However, non-Medicare payers are not legally bound to use the Medicare RBRVS (or its CF) and can establish their own payment methodologies. The AAP private payer advocacy initiative is constantly working with insurers to make certain that payment policies are RBRVS-based and meet the needs of children and their health care providers.

The Medical Home

Both the Medicare program and the enacted ACA are focused on enhancing the quality of services provided to enrollees while controlling non-value-added use of services through an increased emphasis on prevention and chronic disease management. Patient education, medication management, preventive screening, chronic disease case management, and telephone/

electronic patient communication are critical to the success of the medical home model. The AAP is working with other primary care specialties to develop codes and obtain RBRVS valuation for non–face-to-face services while developing evaluation and management codes to permit appropriate payment for disease management, education, and preventive services, all of which are crucial to chronic care management.

APPLICABILITY TO PEDIATRICS

Although coding and payment policies are primarily driven by the adult Medicare component of the CMS, recently both *CPT* and the RUC have been much more responsive to the needs of pediatric patients. However, if access to efficient and effective health care for all children is to be ensured, Medicaid and other payers must recognize and pay for all of the *CPT* codes, including those for immunization administration, non–face-to-face services, and children's screening services. The AAP believes that it is essential that the CMS publish values for all codes valued by the RUC, including those that may not be applicable to the adult Medicare population, but are still essential for comprehensive pediatric care.

National Correct Coding Initiative

Under provisions outlined in the ACA, Medicaid agencies must use Medicare's National Correct Coding Initiative (NCCI) edits to determine payment policy. The CMS developed the NCCI to promote national correct coding and to control improper coding, which had been resulting in inappropriate payments for Medicare Part B claims. NCCI policies are based on coding conventions defined in *CPT* guidelines, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practices, and

review of current coding practices. The AAP is provided an opportunity to review and comment on these edits before their publication, giving the pediatric community 1 more opportunity to advocate that children's access to needed services not be compromised by exclusively adult-oriented payment decisions.

Pediatric National Payment Representation

The AAP has representation on the *CPT* Editorial Panel, the RUC, the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* Editorial Advisory Board, and the *International Classification of Diseases, Eleventh Revision (ICD-11)*, Pediatric Topic Advisory Group. This representation provides the AAP with a consistent voice, respected by adult specialty society colleagues and national payers. State- and payer-specific payment decisions that conflict with national rules or policies and that disadvantage children are being addressed through the active involvement of AAP members, state AAP chapters, and AAP chapter pediatric councils.

The ACA has also recognized the importance of services to children by mandating that, by 2014, all Medicaid programs use the Medicare CF as the floor for a large percentage of services provided in the office by primary care physicians. Although the AAP supports this attempt to equalize payments for services provided to adults and children, it continues to advocate for inclusion of all evaluation and management and procedural services provided to children and for a base Medicaid CF for pediatric services that exceeds Medicare's base to ensure that all children have access to care in a medical home. In addition, the AAP supports the development of a value-based reimbursement system that will additionally reward practices

and providers that demonstrate high quality and superior health outcomes in the patients they serve.

National Pediatric Database

The Medicare system uses a single national database (Medicare Part B Database) to track use of services to adults, allowing the CMS to identify policy and payment changes that negatively affect access to services or identify overuse of new or high-cost services. The absence of a single national database for Medicaid makes similar analyses for pediatric care challenging or impossible and limits important research tracking relationships between pediatric access to care, use of services, and quality outcomes. The AAP continues to actively lobby for a single national Medicaid database.

COMPONENTS OF THE RBRVS PAYMENT SYSTEM

The RBRVS system assigns a numeric value to each of 3 RBRVS components:

- Physician work
- Practice expense
- Professional liability insurance expense

Physician Work

The work a physician expends in directly providing a service or performing a procedure is called "intra-service work." In the office setting, the intra-service period is defined as face-to-face patient encounter time. In the hospital setting, it is the time spent on the patient's unit or floor, and for surgical procedures, it is the period from initial incision to the closure of the incision. Work performed before and after provision of a service is referred to as "pre-service work" and "post-service work," respectively. When pre-service, intra-service, and post-service works are combined, they create the

“total work” involved in the provision of that service.

Practice Expense

The practice expense component of the RBRVS includes the cost of clinical staff time, medical supplies, and medical equipment. In aggregate, practice expense accounts for an average of 44.8% of a code's total RVU. Increased paperwork, reporting regulations (eg, immunization registries and reportable quality indicators), and expenses involved in transitioning to electronic health records are common to all pediatric practitioners. The practice expense values for an office (non-facility) service will be higher than those for services provided in a hospital or other facility not owned by the provider, because much of the facility practice expense is covered under Medicare Part A, and physician services are covered under Medicare Part B; hence, some procedures have differing RVUs depending on whether they are performed in a “facility” as opposed to the practitioner's office.

Since 1998, the CMS has used a formula for calculating practice expense that allocates the costs of providing a specific service uniformly across all specialties by using expert panels to decide each of 6 categories of costs involved in each type of patient encounter: clinical labor, medical supplies, medical equipment, office expense, administrative labor, and all other expenses.

Professional Liability Insurance Expense

RBRVS assigns RVUs to cover the professional liability insurance expense incurred by physicians in providing each service. Similar to practice expense, these costs are normalized for all specialties providing that service.

Geographic Practice Cost Indices

The Omnibus Budget Reconciliation Act of 1989 also introduced the concept of

geographic practice cost indices to address the disparity in the cost of living in urban (37% higher) versus rural practices. Each component of the total RVU (physician work, practice expense, and professional liability insurance) is subjected to different correction values with states varying in the number of regions that are assigned different geographic practice cost indices.

RBRVS CONVERSION

Conversion from RVUs to payment amounts is a multistep process that is covered in detail in the RBRVS Brochure and RBRVS Conversion Spreadsheet from the AAP.

HIPAA CODE SETS AND DISEASE CLASSIFICATION

HIPAA established standard transaction codes for medical claims submission. The primary codes for reporting physician encounters include the Healthcare Common Procedure Coding System (HCPCS) Level I and Level II codes for procedural reporting and the *ICD-9-CM* codes for diagnosis reporting.

The *International Classification of Diseases* (ICD),² published by the World Health Organization, is used to code for a diagnosis, symptom, condition, or event linked to a provided service. The current clinical modification in the United States (ie, *ICD-9-CM*)¹ has been in use since 1979. Conversion to *ICD-10-CM*, in use internationally since 1994, is expected in the United States on October 1, 2015. The 7-digit alphanumeric system of *ICD-10-CM* allows for greater specificity for tracking illnesses, injuries, and disease-management programs. The AAP supports this transition to *ICD-10-CM* and is well positioned within the World Health Organization topical advisory groups to ensure that the Eleventh Revision of the ICD contains accurate, current, and comprehensive pediatric diagnoses and nomenclature.

HCPCS Level I Codes: CPT

HCPCS Level I codes are also called *CPT* codes. *CPT* is a listing of descriptive terms and identifying codes for reporting medical services and procedures developed and maintained by the American Medical Association. The *CPT* nomenclature comprises 3 categories of codes.

Category I CPT Codes

Category I *CPT* codes describe a procedure or service identified with a 5-digit *CPT* code and descriptor nomenclature. Category I *CPT* codes must represent services or procedures that are approved by the Food and Drug Administration, widely used in practice, and evidence based.

Category II CPT Codes

Category II *CPT* codes are supplemental tracking codes, without assigned RVUs, that are used to report adherence to quality indicators, adherence to clinical guidelines, and suggested best practices. Their use is encouraged, although not required. When reported, they facilitate quality data collection that support nationally established performance measures.

Category III CPT Codes

Category III *CPT* codes are temporary tracking codes, also without assigned RVUs, that allow for tracking new and emerging technologies while further studies determine whether they have sufficient use and more convincing literature support to qualify as Category I *CPT* codes.

HCPCS Level II Codes

HCPCS Level II codes, commonly referred to as HCPCS (“hick-picks”) codes, are used to identify services not included in the *CPT* nomenclature (eg, ambulance services, durable medical equipment, prosthetics, orthotics, and supplies)

that are developed and assigned by the CMS without direct input from the specialty societies. HCPCS Level II codes are alphanumeric codes, consisting of a single alphabetical letter followed by 4 numeric digits and are used to report office supplies such as injectable drugs and inhalation solutions as well as some orally administered drugs.

RECOMMENDATIONS

1. In the absence of more global reimbursement systems, the principles embodied by the fully implemented RBRVS system should continue to be the preferred process to establish physician payment, while recognizing a need to strive toward more parity between cognitive and procedural services, including complex chronic care, behavioral/mental health, and non-face-to-face services.
2. RBRVS values for CPT codes should accurately reflect the complexity of both cognitive and procedural physician work, comprehensive practice expense, and professional liability insurance expense in providing services

to infants, children, adolescents, and young adults.

3. The CMS should publish all RUC-recommended values, not just those that are applicable to the Medicare population.
4. The RUC process should accurately assess the nonprocedural physician work, practice expense, and professional liability insurance expense included in the provision of health care services to infants, children, adolescents, and young adults. To accomplish this, the RUC survey instrument, which is used to obtain estimates of the time and complexity required in performing a procedure to estimate a recommended professional work value, should be revised to allow for the accurate valuation of nonprocedural cognitive services.
5. Nationally, the education of pediatricians and pediatric subspecialists within AAP entities should be pursued to better understand the RUC survey instrument and the elements of physician work toward encouraging robust RUC survey participation among AAP members.

6. All payers, including Medicaid, should pay for the full spectrum of CPT codes and recognize CPT guidelines.

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Atopic Dermatitis: Skin-Directed Management

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- *Clinical Report*

CLINICAL REPORT

Atopic Dermatitis: Skin-Directed Management

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SECTION ON DERMATOLOGY

KEY WORDS

atopic dermatitis, eczema, skin care, treatment, topical
corticosteroids

ABBREVIATIONS

ACD—allergic contact dermatitis

AD—atopic dermatitis

IgE—immunoglobulin E

MRSA—methicillin-resistant *Staphylococcus aureus*

NIAID—National Institute of Allergy and Infectious Diseases

QoL—quality of life

TCl—topical calcineurin inhibitor

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abstract

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Atopic dermatitis is a common inflammatory skin condition characterized by relapsing eczematous lesions in a typical distribution. It can be frustrating for pediatric patients, parents, and health care providers alike. The pediatrician will treat the majority of children with atopic dermatitis as many patients will not have access to a pediatric medical subspecialist, such as a pediatric dermatologist or pediatric allergist. This report provides up-to-date information regarding the disease and its impact, pathogenesis, treatment options, and potential complications. The goal of this report is to assist pediatricians with accurate and useful information that will improve the care of patients with atopic dermatitis. *Pediatrics* 2014;134:e1735–e1744

Atopic dermatitis (AD), commonly referred to as eczema, is a chronic, relapsing, and often intensely pruritic inflammatory disorder of the skin. A recent epidemiologic study using national data suggested that the pediatric prevalence is at least 10% in most of the United States.¹ AD primarily affects children, and disease onset occurs before the ages of 1 and 5 years in 65% and 85% of affected children, respectively.¹

The number of office visits for children with AD is increasing.² Up to 80% of children with AD are diagnosed and managed by primary care providers, often pediatricians.³ Although medical subspecialists, such as pediatric dermatologists and/or pediatric allergists, may be suited to provide more advanced care for children with AD, lack of a sufficient number of such physicians, particularly pediatric dermatologists,⁴ likely means the burden of AD care will continue to fall to primary care providers. Although consensus guidelines and practice parameters regarding the management of AD in children have been published,^{5–10} considerable variability persists in clinical practice, particularly regarding the roles that bathing, moisturizing, topical medications, and allergies play in management. Inconsistencies in opinion and treatment approach as well as the chronic and relapsing nature of AD can lead to frustration for the patient, family, and primary care providers when managing AD.

STATEMENT OF THE PROBLEM

New data support the theory that AD results from primary abnormalities of the skin barrier,¹¹ suggesting that skin-directed management of AD is of paramount importance. This clinical report reviews AD and provides an up-to-date approach to skin-directed management that is based on pathogenesis. Effectively using this information to create treatment plans

and educate families should help pediatric primary care providers manage most children with AD, thereby improving patient satisfaction and clinical outcomes.

CLINICAL FEATURES

The diagnosis of AD is primarily clinical (Table 1). Major clinical features are a pruritic and relapsing eczematous dermatitis in a typical distribution that changes with age.⁹ In infancy, the cheeks, scalp, trunk, and extremities are most commonly affected. In early childhood, the flexural areas are characteristic, whereas in adolescents and adults, hands and feet are typically involved. Pruritus is a hallmark of AD, which is often referred to as the “itch that rashes.” Other features that support the diagnosis of AD include early age of onset, personal or family history of atopy, ichthyosis vulgaris, and/or xerosis. It is important to exclude other inflammatory skin conditions, such as contact dermatitis, seborrheic dermatitis, and psoriasis. Skin biopsies and laboratory testing are usually unnecessary and not helpful in making the diagnosis of AD, although they may be beneficial when trying to exclude

conditions that appear similar to AD (such as those mentioned previously), particularly in patients whose symptoms are not responding to standard skin-directed care.

EFFECTS ON QUALITY OF LIFE

The effects of AD on the quality of life (QoL) of patients and their families cannot be underestimated. Nearly 50% of children with AD report a *severely* negative effect of the disease on QoL.¹² Factors that contribute to poor QoL in AD are fatigue and sleep deprivation (which directly correlate with itch and severity of AD), activity restriction, and depression. Children with severe AD also tend to have fewer friends and participate in fewer group activities than their peers.¹³ These children may be at higher risk of depression, anxiety, and other mental health disorders.¹⁴

AD also has a negative effect on QoL of caregivers and parents of affected children.¹⁵ Parents of children with moderate and severe AD spend up to 3 hours per day caring for their children's skin. The most commonly reported negative effects on parents are lack of sleep (often because of cosleeping), fatigue, absence of privacy (because of cosleeping, disrupted sleep of affected children), treatment-related financial expenditures, and feelings of hopelessness, guilt, and depression. In fact, the depression rate in mothers of children with AD is twice as high as in mothers of children with asthma.¹⁶ Appropriate social and community support resources, such as referral to a counselor, psychologist, or patient support groups, such as the National Eczema Association (www.nationaleczema.org), can be helpful when QoL issues are encountered in patients and families with AD.

PATHOGENESIS

The pathogenesis of AD is complex and multifactorial. Skin barrier dysfunction,

environmental factors, genetic predisposition, and immune dysfunction all play a role in its development and are closely intertwined. In the past, emphasis had been placed on T helper cell dysregulation, production of immunoglobulin E (IgE), and mast cell hyperactivity leading to the development of pruritus, inflammation, and the characteristic dermatitis.¹¹ Recent discoveries, however, have established the key role of skin barrier dysfunction in the development of AD.¹⁷

The primary function of the skin barrier is to restrict water loss and to prevent entry of irritants, allergens, and skin pathogens. The outermost layer of skin, called the stratum corneum, is critical to the integrity of the skin barrier, with the protein filaggrin being a key player in stratum corneum structure and formation.¹⁸ Loss-of-function mutations (of which more than 40 have been described) in *FLG*, which encodes filaggrin, have been implicated in up to 50% of patients with moderate to severe AD in some demographic populations.^{17,19} Mutations in *FLG* are associated with a two- to threefold increased risk of having AD.²⁰

There are several proposed mechanisms of how filaggrin defects contribute to the development of AD. Inadequate filaggrin production leads to a reduced ability of keratinocytes to maintain hydration and to restrict transepidermal water loss, which then leads to xerosis, which in turn produces pruritus and, subsequently, AD.²¹ An inadequate skin barrier might also allow for the entry of aeroallergens, leading to an inflammatory response, causing AD. Another theory speculates that local pH may be changed with an altered skin barrier, leading to the overgrowth of bacteria, such as *Staphylococcus aureus*, which then may trigger an innate immune response, leading to the development of inflammatory skin lesions. Regardless of the mechanism,

TABLE 1 Clinical Features in AD^{5,6,9}

Major clinical features
Itching/pruritus
Typical dermatitis with a chronic or relapsing history
Patient or family members with atopy
Typical distribution and age-specific patterns
Minor clinical features
Early age of onset
Dry skin/xerosis
Keratosis pilaris
Ichthyosis vulgaris
Lip dermatitis
Hand eczema
Lichenification
Elevated IgE level
Itching on sweating
Recurrent infections
Pityriasis alba
Dermatographism
Eye symptoms: cataracts, keratoconus, inflammation

this new knowledge reinforces the primary role of the skin barrier in the pathogenesis of AD and highlights the need for skin-directed therapy to repair or enhance the function of the skin barrier.

ALLERGIES AND AD

The relationship between AD and food allergy is complex but likely over-emphasized. More than 90% of parents incorrectly believe that food allergy is the sole or main cause of their child's skin disease.²² The resulting focus on food allergy can result in elimination diets; potential nutritional concerns, such as protein or micronutrient malnutrition or deficiencies; and misdirection of treatment away from the skin, thereby leading to undertreatment. Effective treatment of the skin tends to allay parental concern regarding food allergy.²³

True food-induced AD is rare. The most common cutaneous manifestations of food allergy are often IgE-mediated and consist of acute urticaria, angioedema, contact reactions, or in some cases, an increase in AD symptoms.^{24,25} In the case that AD is worsened by exposure to a food allergen, these reactions are not IgE-mediated but rather delayed-type hypersensitivity reactions and usually develop 2 to 6 hours after the exposure to the food.²⁶

The accentuated role of food allergies in AD may stem from the observation that food allergies are prevalent in patients with AD. The prevalence of food allergy in all children in the first 5 years of life is approximately 5%.²⁴ In children with AD, however, the prevalence of food allergy is approximately 30% to 40%,²⁵ and up to 80% will have high food-specific IgE concentrations, even in the absence of a true food allergy.²⁷ In addition, patients who have food allergy often have earlier-onset and more severe AD, and patients with early-onset AD have a higher

risk of developing food allergies than those with later-onset AD.²⁸ However, it is important to stress that this relationship is not causative. Rather, the presence of food allergy predicts a poor prognosis of severe and persistent AD, but food allergy does not necessarily cause AD.

Recent guidelines set forth by the National Institute of Allergy and Infectious Diseases (NIAID) support this position. In these guidelines, the NIAID states: "In some sensitized patients...food allergens can induce urticarial lesions, itching and eczematous flares, all of which may aggravate AD" but do not cause AD. They also state that, in the absence of documented IgE- or non-IgE-mediated food allergy, there is "...little evidence to support the role for food avoidance" in the treatment of AD.²⁵ Egg allergy may be one exception, as up to half of infants with egg-specific IgE may have improvement in their AD when following an egg-free diet.²⁹ The NIAID guidelines state that allergy evaluation (specifically to milk, egg, peanut, wheat, and soy) should be considered in children younger than 5 years with severe AD if the child has persistent AD despite optimal management and topical therapy or if the child has a reliable history of an immediate cutaneous reaction after ingestion of a specific food.

The "atopic march" is the concept that AD is the first stop in the progression to other allergic disorders, such as asthma and allergic rhinitis.³⁰ It has been suggested that early optimal and successful treatment of AD may prevent or attenuate the development of other atopic conditions.³¹ The recent findings of the role *FLG* mutations play in causing epidermal barrier defects, thus allowing for the entry of aeroallergens and other allergens into the skin and subsequent epicutaneous sensitization, lends strong support to this possibility and highlights the importance of effective skin-directed treatment of AD.

Allergic contact dermatitis (ACD) is a delayed hypersensitivity reaction to cutaneous allergens that is underestimated in the pediatric population and likely plays a greater role in perpetuating AD than was previously believed. Up to 50% of children with difficult-to-control AD have at least 1 positive patch test reaction to a cutaneous allergen.³² Not all positive reactions may be relevant, however. Most studies estimate 50% to 70% of all positive reactions to be relevant in patients with suspected ACD. Thus, the possibility of ACD should be considered in children with unusual or difficult-to-control AD.

TREATMENT PRINCIPLES

Skin-directed therapies should be the first approach to management. This approach has 4 main components, each focusing on a specific manifestation of AD: (1) maintenance skin care, designed to repair and maintain a healthy skin barrier; (2) topical antiinflammatory medications, to suppress the inflammatory response; (3) itch control; and (4) managing infectious triggers, recognition and treatment of infection-related flares. Education of patients and families is another critical factor that should not be overlooked. AD is a frustrating disease because of its recurrent nature, even in the face of excellent care plans. When the primary care provider is able to set realistic expectations regarding outcomes, parental compliance is better and frustration is decreased. It can be helpful to discuss the prognosis of AD, because most children will outgrow the symptoms or at least the severity of the disease.²⁷ Patients whose parents receive comprehensive education regarding AD and its care have better improvement in AD severity than patients whose parents do not receive this education.³³ Written action plans have been shown to improve adherence in children with asthma, and a similar

model for patients with AD (see Fig 1 for an example), outlining specific indications for different products and medications, is likely to be helpful.^{34,35}

Maintenance Skin Care

Maintenance skin care is the foundation of AD management; its goal is to repair and maintain a functional skin barrier. Patients should be instructed to develop these habits and perform them daily. Preliminary evidence supports the role of maintenance skin care in helping to reduce both the frequency and severity of AD flares. The key facets of maintenance care include maintaining skin hydration and avoiding irritants and triggers.

The optimal frequency of bathing for children with AD has not been well

studied and remains controversial. Soaking baths allow the skin to imbibe moisture, and a daily bath can be beneficial in patients with AD as long as a moisturizer is applied afterward.^{30,36} The specific frequency of bathing should be titrated to the individual patient and his or her response to bathing. The use of lukewarm water and limiting the duration of the bath can prevent skin dehydration. Cleansing may also remove bacteria from the skin surface. A mild synthetic detergent without fragrance can be used to cleanse soiled areas without fear of exacerbating the skin disease. Additives are not proven to be effective, although dilute bleach can be helpful for patients who are prone to infection

and flares (see Managing Infectious Triggers).

A second and extremely important component of maintaining skin hydration is lubrication of the skin, commonly referred to as moisturization. Frequent moisturization alleviates the discomfort associated with xerosis, helps to repair the skin barrier, and reduces the quantity and potency of pharmacologic interventions.^{37,38} In a British study evaluating 51 children with AD, parents were educated on the proper use of moisturizers and topical treatments by a nurse specialist. During the study period, the quantity of moisturizer used increased 800% (average use of 426 g per week per patient) while the severity of AD decreased and the percentage of patients having to use moderate or potent topical steroids decreased.³⁹

Studies comparing the relative effectiveness of specific moisturizers are lacking, and the plethora of products can make the task of choosing a moisturizer daunting. Simplistically, all moisturizers are mixtures of lipid (liquid or semisolid) and water. Ointments have the highest proportion of lipid (for example, petroleum jelly is 100% lipid) and likewise feel “greasy” when applied to the skin. Creams are emulsions of water in lipid (oil>water) and contain preservatives and stabilizers to keep these ingredients from separating. Although creams can be less greasy than ointments, the added ingredients can sometimes burn or sting atopic skin. Similarly, lotions are also emulsions with a higher proportion of water to lipid than creams. Frequent reapplication of lotions is needed to maintain skin hydration. In general, ointments tend to have the greatest moisturizing effect, followed by creams, and then lotions. The best moisturizers for patients with AD are fragrance free and have the least possible number of preservatives, because these are potential irritants.

An Action Plan to Guide the Care of Your Child's Atopic Dermatitis (Eczema)

1. If your child enjoys a bath, allow him or her to soak daily in lukewarm water for 10 to 15 minutes. If your child does not enjoy a bath or if you feel water irritates his or her skin, bathe every 2 to 3 days. Use a gentle cleanser for dirty areas only at the end of the bath.
2. After the bath, pat the skin dry, leaving it damp to the touch.
3. Prescription medications should be applied to areas of the skin that are red, rough, and itchy. These medications should be applied in a thin layer.
 - Apply _____ to affected areas of the face, neck, armpits, and groin.
 - Apply _____ to affected areas of the body.
4. Apply a moisturizer (preferably a cream or ointment) over the entire face and body. Your child's skin medications and moisturizer should be put on within a few minutes after the bath so the skin does not dry out.
5. Repeat steps 3 and 4 a second time each day if instructed by your doctor.
6. Moisturizer can be applied as often as needed to dry, itchy skin. Prescription skin medications should not be used more than 2 times daily.
7. Continue the prescription skin medications until the red, rough rash is gone. If the flare of the rash has not improved in 2 weeks, talk with your doctor.
8. After the rash has cleared, continue to moisturize all areas of the face and body daily.
9. Restart the prescription skin medications as directed when the rash returns.
10. Antihistamines can help with itching and poor sleep due to eczema.
 - Give _____ 30 minutes before bedtime when your child is itchy.
 - Give _____ in the morning as needed for itching.
11. Oozing, drainage, pus bumps, and yellow crusts can indicate the skin is infected. Talk with your doctor right away if you are concerned about skin infection.

FIGURE 1

An action plan for the management of AD.

Moisturizers should be applied at least once daily to the entire body, regardless of whether dermatitis is present. There are a handful of prescription barrier creams marketed for the treatment of AD. These products do not have active pharmacologic ingredients. A small study compared 2 of these products with an over-the-counter ointment and revealed no significant difference in efficacy for patients with mild-to-moderate AD, as defined by investigator global assessment.⁴⁰ Although no major adverse effects have been reported with these products, they are considerably more expensive and may, therefore, be less cost effective than standard moisturizers.

Multiple patient-specific factors, commonly referred to as triggers, may exacerbate AD. Triggers may be unavoidable, but minimizing exposure to them can be helpful. Common triggers may include aeroallergens or environmental allergens, infections (particularly viral illnesses), harsh soaps and detergents, fragrances, rough or non-breathable clothing fabrics, sweat, excess saliva, and psychosocial stress.

Topical Antiinflammatory Medications

The eczematous dermatitis seen in AD is the manifestation of an inflammatory immune response in the skin. Flares of dermatitis are unlikely to respond to moisturization alone, and during these times, treatment is focused on suppressing the inflammatory response. Topical steroids are the first-line, most commonly used medications to treat active AD and have been used for the last 40 to 50 years.³⁰ When used appropriately, they are effective and safe.⁴¹ However, when used inappropriately, there are potential risks of cutaneous atrophy, striae, telangiectasia, and systemic absorption with resulting adrenal suppression. There are also other potential

local effects when used around the eyes (intraocular hypertension, cataracts) or mouth (periorificial dermatitis). Because of these potential risks, there is a real phenomenon of “steroid phobia” on the part of both parents and health care providers. Although this phobia does not correlate with AD severity, it does lead to undertreatment of the skin disease.^{42,43}

Topical steroids are classified according to their potency, ranging from class VII (low potency) to class I (super potent; Table 2). Class I medications are 1800 times more potent than the least potent class VII medications. Risk of adverse effects directly correlates with potency, with high-potency and super-potent topical steroids carrying the greatest risk. When treating most cases of AD, high-potency medications are generally not needed. Patients treated with higher-potency topical steroids are at risk for developing the aforementioned adverse effects, making close follow-up necessary. Choosing an appropriate topical steroid can be difficult, given the number of different medications, and health care providers are advised to rely on 2 or 3 medications from the low- (classes VI and VII) and moderate-potency groups (classes III, IV, and V) as “go-to” medications for everyday practice. These choices may be based on regional prescribing practices and insurance coverage or cost. Inexpensive low- and moderate-potency generic topical steroids are hydrocortisone and triamcinolone, respectively. Acceptable “limits” of topical steroid potency in a primary care practice are low-potency topical steroids for the face, neck, and skin folds and moderate-potency topical steroids for the trunk and extremities.

For acute flares and moderate to severe cases, wet wrap therapy (also called wet dressings) can be used in conjunction with topical steroids to

TABLE 2 Topical Steroid Medications by Class

Class I: Superpotent
Clobetasol propionate 0.05% ointment, cream, solution, and foam
Diflorasone diacetate 0.05% ointment
Fluocinonide 0.1% cream
Halobetasol propionate 0.05% ointment and cream
Class II: High potency
Betamethasone dipropionate 0.05% ointment and cream
Budesonide 0.025% cream
Desoximetasone 0.25% ointment and cream
Diflorasone diacetate 0.05% cream
Fluocinonide 0.05% ointment, cream, and gel
Halcinonide 0.1% cream and ointment
Mometasone furoate 0.1% ointment
Class III: Moderate potency
Betamethasone valerate 0.1% ointment, foam
Desoximetasone 0.05% cream
Diflorasone diacetate 0.05% cream
Fluticasone propionate 0.005% ointment
Triamcinolone acetonide 0.1% ointment
Triamcinolone acetonide 0.5% cream
Class IV: Moderate potency
Betamethasone valerate 0.12% foam
Clocortolone pivalate 0.1% cream
Flurandrenolide 0.05% ointment
Fluocinolone acetonide 0.025% ointment
Halcinonide 0.025% cream
Hydrocortisone valerate 0.2% ointment
Mometasone furoate 0.1% cream and lotion
Triamcinolone acetonide 0.1% cream
Class V: Moderate potency
Betamethasone valerate 0.1% cream
Clocortolone pivalate 0.1% cream
Flurandrenolide 0.025% ointment
Flurandrenolide 0.05% cream
Fluocinolone acetonide 0.01% cream
Fluocinolone acetonide 0.025% cream
Hydrocortisone butyrate 0.1% ointment, cream, and lotion
Hydrocortisone probutate 0.1% cream
Hydrocortisone valerate 0.2% cream
Prednicarbate 0.1% cream
Triamcinolone 0.025% ointment
Class VI: Low potency
Alclometasone dipropionate 0.05% ointment and cream
Desonide 0.05% ointment, cream, lotion, hydrogel, and foam
Fluocinolone acetonide 0.01% oil
Flurandrenolide 0.025% cream
Triamcinolone acetonide 0.025% cream
Class VII: Low potency
Hydrocortisone 0.5% and 1% ointment and cream (over the counter)
Hydrocortisone 2.5% ointment, cream, and lotion

quickly control the dermatitis.⁴⁴ Wet dressings increase penetration of topical steroids into the skin, decrease

itch, and serve as an effective deterrent to scratching. The technique is straightforward: after a soaking bath, topical steroid is applied to affected areas followed by application of moisturizer to the rest of the skin; moist gauze or cotton clothing that has been dampened with warm water is then applied; the wet layer is covered with dry cotton clothing. Blankets and a warm room keep the child comfortable. The dressings can be left in place for 3 to 8 hours before being changed. Wet dressings can be used continuously for 24 to 72 hours or overnight for up to 1 week at a time.

Another consideration when prescribing topical steroids is the vehicle or form of product by which the active ingredient is delivered. Ointments are less likely to produce a burning or stinging sensation and are better tolerated by infants and younger children. When comparing the same active ingredient and concentration, ointments are more effective than creams or lotions, because their occlusive effect results in a higher relative potency. Topical steroids should be applied as a thin layer once or twice daily to affected areas until these areas are smooth to touch and no longer red or itchy. Traditionally, topical steroids are held when dermatitis is quiescent and restarted when the eruption recurs. Placing an absolute limit on the duration of topical steroid use can be confusing for families, leads to unsatisfactory outcomes, and conflicts with the relapsing nature of the disease itself. However, if AD is not responding after 1 to 2 weeks of treatment, reevaluation to consider other diagnoses or treatment plans is indicated. When these general guidelines are followed, the risk of adverse effects from the use of topical steroids is extremely low.

Topical calcineurin inhibitors (TCIs) are a newer treatment of AD. These medications are topical immunosuppressive

agents that inhibit T-cell function. There are currently 2 forms: tacrolimus ointment (available in 0.03% and 0.1%) and pimecrolimus 1% cream. Both are approved as second-line therapy for moderate-to-severe AD. A recent meta-analysis in pediatric patients with AD demonstrated that both tacrolimus and pimecrolimus are effective; tacrolimus is more effective than pimecrolimus, but both reduce the inflammation and pruritus associated with AD.⁴⁵

TCIs have a different adverse effect profile than topical steroids and do not cause atrophy, striae, telangiectasia, and adrenal suppression. Thus, they are highly beneficial to treat AD in patients for whom concerns for adverse effects from long-term use of topical steroids are highest (eg, face, eyelids). The negatives, however, are a higher relative cost and the potential adverse effects of burning and stinging (tacrolimus > pimecrolimus). In addition, the Food and Drug Administration has issued a so-called “black box” or boxed warning for TCIs, citing a potential cancer risk with the medication, on the basis of the observation that laboratory animals exposed to high doses of systemic calcineurin inhibitors developed malignancies more frequently and on rare case reports of adult patients using TCIs who developed lymphoma and skin cancers.⁴⁶ However, the cause-and-effect relationship between TCI use and malignancy in these case reports is unclear. Reassuringly, TCIs have been used in children for more than 15 years, there have been no reports of malignancy in children, and there is little to no concern for systemic absorption or systemic immunosuppression.⁴⁷ Indeed, in 1 adult study, there was a lower rate of nonmelanoma skin cancer in patients with AD who used TCIs to treat their inflammatory disease.⁴⁸

Proactive Treatment

Although traditional AD management consists of treating active disease and flares with topical steroids and/or TCIs,

emerging data suggest that use of these medications when a patient is not having active disease may be helpful as well. In 1 study, patients used twice-daily antiinflammatory medications to treat active AD and were then randomly assigned to receive “proactive” twice-weekly treatment with topical tacrolimus or placebo. Patients who received topical tacrolimus had significantly less AD flares and increased time to new flare development when compared with those who received placebo.⁴⁹ A similar effect may also be true with topical steroids (fluticasone propionate and methylprednisolone aceponate have been studied),⁵⁰ although none of these studies have evaluated the long-term safety of this treatment regimen. The choice of medication used for flare prevention may depend on patient age, location of involvement, and cost.

Itch Control

Pruritus is another important component of AD. AD is commonly referred to as the itch that rashes; the associated pruritus may be significant, even in the absence of significant rash. Often, parents may be unaware of how much their child scratches, because itching is generally worse at night. The pathophysiology behind pruritus is complex, and both peripheral and central factors are involved.⁵¹ Examples of peripheral factors are irritant entry through a defective epidermal barrier, transepidermal water loss, and protease activity in the skin.⁵² Centrally, there is a complex interplay of multiple different mediators, although histamine seems to have a limited role, if any.^{52,53} Clinical factors can also promote itch, including scratching (the “itch-scratch” cycle), xerosis, psychological stress, sweat, and contact with irritants such as wool and aeroallergens.

It is often challenging to remove itch, even when a patient's skin is improving. Management of itch initially focuses on

minimizing triggers and continuing the skin-directed treatments of restoring the skin barrier and suppressing inflammation. Adjunctive systemic therapy can be added to help manage itch. Oral antihistamines do not have a direct effect on the dermatitis, but can help reduce the sensation of itching and, thus, decrease scratching and trauma to the skin in patients with AD flares.⁵⁴ Sedating antihistamines (such as diphenhydramine or hydroxyzine) should be used with caution in infants, who may be more prone to adverse effects of these agents. In addition, paradoxical effects of agitation instead of sedation may occur in some children. Nonsedating antihistamines (such as cetirizine and loratadine) are less effective on pruritus but can be helpful for patients who have environmental allergic triggers.⁵⁴ Topical antihistamines are not effective in the treatment of AD-associated pruritus and contain potential irritants and allergens that may worsen dermatitis.

Managing Infectious Triggers

Both bacterial and viral skin infections are associated with flares in children with AD. Affected patients, particularly those with poorly controlled AD, have a higher risk of cutaneous infections. The skin of patients with AD has an abnormal expression of antimicrobial peptides responsible for responding to bacteria or skin barrier compromise, toll-like receptor defects, and immune dysregulation in the form of diminished immune cell recruitment.⁵⁵ This combination of factors puts patients with AD at higher risk of skin infection.

Ninety percent of patients with AD are colonized with *S aureus*.⁵⁶ Pruritus may occur even in patients who are colonized but not actively infected. Many patients with AD have sudden exacerbations of their disease that can be attributed to active infection with bacteria, most commonly *S aureus*,

and active treatment of the infection subsequently improves the skin.⁵⁶ Clinical signs of infection, such as pustules, oozing and honey-colored crusts, and less commonly fever and cellulitis, may lead the primary care provider to prescribe antibacterial treatment. Secondary infection of AD is a clinical diagnosis and is often associated with flare of the underlying AD. Obtaining skin cultures, particularly of pustules and draining lesions, before treatment can be helpful in determining the causative pathogen but is not always necessary. The rate of methicillin-resistant *S aureus* (MRSA) colonization in patients with AD varies depending on the community in which the patient resides.⁵⁷ Streptococcal infections may also occur in patients with AD. Signs of streptococcal infection include pustules, painful erosions, and fever. In addition, patients may have facial or periorbital involvement and invasive infections.⁵⁸

There are multiple synergistic components involved in treating active *S aureus* and streptococcal infection in AD. Topical, oral, or intravenous antibiotic therapy may be needed depending on the extent and severity of infection. The specific medication used should be directed at *S aureus* and *Streptococcus*. Topical mupirocin can be used for limited skin lesions. Cephalixin is a common first-choice when oral antibiotics are needed and MRSA is not suspected. Repair of the skin barrier is continued simultaneously: bathing, moisturization, and topical anti-inflammatory therapies are all usually indicated. MRSA or other etiologies may be considered in patients who remain refractory to treatment.

Dilute bleach baths may have a useful role in the management of patients with AD, particularly those prone to recurrent infection and AD flares. A recent placebo-controlled, blinded study examined the effects of 0.005% bleach

baths plus intranasal mupirocin versus placebo in children with moderate to severe AD. Patients bathed for 5 to 10 minutes twice weekly with the intervention. Those in the treatment group had significant improvement in their AD severity scores versus those in the placebo group.⁵⁶ Areas of the body that were not submerged in the bleach-containing water, specifically the head and the neck, revealed no difference in AD severity scores between the 2 groups. The treatment was well tolerated, without any adverse effect, and without any increase in resistant strains of *S aureus*. Although a relatively small study, the results provide support for the practice of using dilute bleach baths as one modality in the treatment of patients with AD. A concentration of 0.005% bleach is made by adding 120 mL (1/2 cup) of 6% household bleach to a full bathtub (estimated to be 40 gallons) of water. The amount of bleach should be adjusted based on the size of the bathtub and the amount of water in the tub.

Patients with AD are also at greater risk of viral skin infections. These include molluscum contagiosum, eczema herpeticum, the recently described atypical enteroviral infection attributable to Coxsackie virus A6 (the so-called “eczema coxsackieum”),⁵⁹ and vaccinia virus (the virus used in smallpox vaccine). Patients with eczema herpeticum present with shallow, “punched-out” erosions in areas of skin affected with or prone to AD. Similarly, the lesions seen with hand, foot, and mouth disease caused by Coxsackie virus A6 tend to localize to AD skin. In cases in which the diagnosis is not clear, viral studies are indicated.

Eczema herpeticum can be potentially life threatening and requires systemic treatment with acyclovir. In addition, adequate analgesia, skin care, and topical antiinflammatory medications are used. Secondary bacterial infection

often coexists with eczema herpeticum and should be treated appropriately as well. Herpetic keratitis is associated with periocular eczema herpeticum.⁶⁰ Smallpox vaccine uses a live vaccinia virus, and its use was resumed by the military in 2002. Although it is contraindicated for those with AD and in those who have a close contact with AD, rare cases of eczema vaccinatum have been reported. Eczema vaccinatum manifests as a rapidly developing papular, pustular, or vesicular eruption with a predilection for areas of AD, following inadvertent transmission of vaccinia virus from the unhealed inoculation site of the immunized person to a close contact with AD. Systemic dissemination may follow, and case fatality rates range from 5% to 40%. If eczema vaccinatum is suspected, infectious disease experts should be consulted, because treatment with cidofovir may be necessary.⁶¹

Final Points

Using this information, the pediatric primary care provider should be well equipped to treat most children with AD. If patients with suspected AD do not respond to these treatments, referral

to a pediatric medical subspecialist, such as a pediatric dermatologist, may be useful. Other reasons for referral include poorly controlled or generalized AD with consideration for systemic immunosuppressive therapy, recurrent infections (viral or bacterial) in the setting of AD, suspected ACD, and the presence of atypical features or physical examination findings. In cases of persistent, refractory, and/or generalized AD, systemic treatment, such as phototherapy or immunosuppressive medications, may be indicated. Oral steroids are generally not indicated because of their adverse side effect profile and a high likelihood of rebound dermatitis, making ongoing management difficult.

SUMMARY

AD can be a challenging and frustrating chronic disease for pediatric patients, parents, and primary care providers. Although the pathogenesis of AD is complex, recent research advances support the role of an abnormal skin barrier. The clinical corollary to these discoveries is a greater focus on skin-directed therapies as the first-line treatment of children with AD. This

includes maintenance skin care and the use of topical steroids for active disease. Low- and moderate-potency topical steroids are safe and effective for children when used appropriately. Early recognition and treatment of infectious complications can lead to improved patient outcomes. Patient and family education and counseling by the health care provider regarding the pathogenesis, specific treatment, and prognosis of the disease play an extremely important role in the management of AD.

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Attention-Deficit/Hyperactivity Disorder and Substance Abuse

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- *Clinical Report*

CLINICAL REPORT

Attention-Deficit/Hyperactivity Disorder and Substance Abuse

Elizabeth Harstad, MD, MPH, FAAP, Sharon Levy, MD, MPH, FAAP, and COMMITTEE ON SUBSTANCE ABUSE

KEY WORDS

ADHD, attention-deficit/hyperactivity disorder, nonstimulant medication, safe prescribing, stimulant medication, substance abuse

ABBREVIATIONS

AAP—American Academy of Pediatrics
ADHD—attention-deficit/hyperactivity disorder
DSM-5—*Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
OR—odds ratio
SUD—substance use disorder

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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Attention-deficit/hyperactivity disorder (ADHD) and substance use disorders are inextricably intertwined. Children with ADHD are more likely than peers to develop substance use disorders. Treatment with stimulants may reduce the risk of substance use disorders, but stimulants are a class of medication with significant abuse and diversion potential. The objectives of this clinical report were to present practical strategies for reducing the risk of substance use disorders in patients with ADHD and suggestions for safe stimulant prescribing. *Pediatrics* 2014;134:e293–e301

INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurobehavioral disorder of childhood and occurs in approximately 8% of children and youth.^{1,2} It is characterized by deficits in attention in addition to hyperactivity and impulsivity that cause functional impairment in at least 2 settings.³ ADHD is considered a chronic condition.⁴ Stimulant medication is recommended as first-line therapy for school-aged children with ADHD, with implementation of behavioral therapy also recommended. Children with ADHD are at high risk of having co-occurring mental health and behavioral problems, including substance use disorders (SUDs).^{5,6} It is not clear whether stimulant treatment reduces the risk of SUDs in adolescents with ADHD. Some epidemiologic studies have found an inverse association between stimulant treatment and SUDs,^{7,8} although this association was not found in a study that examined the relationship between ADHD, stimulant medication, and conduct disorder.^{9,10} Stimulant medication can also have significant potential for misuse,¹¹ abuse, and diversion^{12,13} (ie, giving away, trading, or selling of prescription medication), which complicates care. Although the potential for misuse and diversion of stimulants has been studied,^{11,12} there is a paucity of recent research on the abuse potential of stimulants among children and adolescents. The objectives of the present clinical report were to review the literature and provide practical suggestions for optimizing ADHD care while minimizing misuse, abuse, and diversion of stimulant medication.

EPIDEMIOLOGY OF SUDS AMONG INDIVIDUALS WITH ADHD

Children and adolescents with ADHD are more likely to misuse alcohol, tobacco, and other illicit substances compared with children without ADHD.^{14,15} In a 2011 meta-analytic review of the prospective association of childhood ADHD and substance use, Lee et al¹⁴ included 27 longitudinal studies that followed up children with and without ADHD into adolescence or adulthood. The following demographic/methodologic factors did not significantly moderate the associations between childhood ADHD and substance outcomes: gender, age, race, publication year, sample source, version of the *Diagnostic and Statistical Manual of Mental Disorders* used to diagnose ADHD, family history of SUD, cognitive impairment, executive dysfunction, and family environment.¹⁶ Lee et al reported that, compared with control subjects without ADHD, children with ADHD were:

- twice as likely to have a lifetime history of nicotine use (odds ratio [OR]: 2.08, $P < .001$);
- nearly 3 times more likely to report nicotine dependence in adolescence/adulthood (OR: 2.82, $P < .001$);
- almost 2 times more likely to meet diagnostic criteria for alcohol abuse or dependence (OR: 1.74, $P < .001$);
- approximately 1.5 times more likely to meet criteria for marijuana use disorder (OR: 1.58, $P = .003$);
- twice as likely to develop cocaine abuse or dependence (OR: 2.05, $P < .001$); and
- more than 2.5 times more likely to develop an SUD overall.

ADHD is associated with an earlier age at onset of substance use and a higher likelihood of use of a variety of substances.^{17–19} Brook et al²⁰ reported that the diagnosis of ADHD poses an increased risk of SUD into adulthood;

meeting criteria for a diagnosis of ADHD in adolescence is associated with developing SUDs in a subject's 20s and 30s. Among individuals with ADHD, the number of inattention and hyperactivity/impulsivity symptoms exhibited is positively correlated with risk of substance use.²¹ Debate exists regarding whether the inattentive versus hyperactive/impulsive subtypes of ADHD confer different risk.^{22–26}

EXPLORING THE BIOLOGICAL AND ENVIRONMENTAL BASIS OF THE RELATIONSHIP BETWEEN ADHD AND SUD

To date, the mechanisms underlying the association between ADHD and SUDs are not completely understood, although several theories have been proposed. Impulsivity is associated with an increased risk of substance use,²⁷ a prerequisite for developing an SUD. It is also possible that impulsivity and poor judgment associated with ADHD contribute to the development of SUDs.²⁸ However, executive functioning deficits and increased substance use seem to be only one piece of the puzzle.²⁹ In addition to difficulty with executive functioning and poor judgment, which may lead to trying substances, individuals with ADHD may also be biologically more vulnerable to developing addiction than their peers without ADHD.

Dopamine transmission is central to current models of both ADHD and SUDs.^{30–32} Compared with unaffected control subjects, individuals with ADHD have greater dopamine transporter density, which may result in rapid clearance and low levels of synaptic dopamine.³³ Drugs of abuse, including cocaine, amphetamine, methamphetamine, Ecstasy, nicotine, alcohol, opiates, and marijuana, all increase synaptic dopamine concentrations, most notably in the brain's reward center, the nucleus accumbens.³⁴

Stimulant medications manage ADHD symptoms by increasing synaptic dopamine concentrations in the striatum (which includes the nucleus accumbens) via presynaptic transporters.³⁵ Theoretically, some individuals with ADHD may use substances to increase synaptic dopamine concentrations as a form of self-medication.³⁶ Another theory proposes a common genetic factor underlying both ADHD and risk of SUDs, although more studies are needed to further evaluate this association.^{37,38}

Children and adolescents with ADHD have higher rates of grade retention and school dropout than those without ADHD.^{39,40} These academic failures may increase an individual's likelihood to use drugs as a means to escape anxiety about school.⁴¹ Academic failures may also cause changes in peer groups, placing the individual with ADHD in social settings with others who have experienced school problems and are at a higher risk of alcohol and drug use.^{42,43}

TREATING ADHD AND CO-OCCURRING MENTAL HEALTH DISORDERS TO REDUCE THE RISK OF SUDS

Treatment of ADHD May Reduce the Risk of SUDs

Treatment of ADHD symptoms with stimulant medication may reduce the risk of developing SUDs.^{7,44} Biederman et al⁴⁵ determined that pharmacotherapy was associated with an 85% reduction in risk of SUDs in youth with ADHD. Timing of treatment matters: children with ADHD who are treated with stimulant medication at a younger age are less likely to use substances than those who have delayed onset of treatment.⁴⁶ Behavioral therapy may also confer some protection against substance use. Findings from the Multimodal Treatment Study of Children with ADHD revealed that

behavioral interventions afforded protection from SUDs at 24 months' post-intervention but not at 36 months.⁴⁷ The optimal age at which to begin treatment of ADHD to decrease the risk of substance use has not been established. The American Academy of Pediatrics (AAP), in its clinical practice guidelines for ADHD,⁴ recommends treating ADHD symptoms in children 6 years and older by using both behavioral interventions and medications approved by the US Food and Drug Administration. The AAP recommends that ADHD symptoms in children as young as 4 years be treated with behavioral interventions and possibly medications. In this context, treatment of ADHD symptoms is recommended as soon as the diagnosis of ADHD is made. Symptoms of ADHD often persist into adulthood,^{48,49} although optimal duration of medication treatment has not been established. Maintaining children on medication while symptoms persist and monitoring for adverse effects seems to be a reasonable approach.

As noted in the AAP clinical practice guidelines for ADHD,⁴ at any point at which a clinician believes that he or she is not adequately trained or is uncertain about making a diagnosis or continuing with treatment, a referral to a pediatric or mental health subspecialist should be made. If a diagnosis of ADHD or other condition is made by a subspecialist, the primary care clinician should develop a management strategy with the subspecialist which ensures that the child will continue to receive appropriate care consistent with a medical home model wherein the primary care clinician partners with parents so that both health and mental health needs are integrated.

Treating Co-occurring Mental Health Disorders

Co-occurring mental health conditions are common in individuals with ADHD and are associated with increased SUD

risk. Brook et al²⁰ determined that conduct disorder mediated the association of ADHD and SUDs. Other studies have revealed that, even after controlling for conduct disorder, ADHD symptoms are associated with increased risk of both substance use and development of SUDs.^{18,25} Comorbid conditions, including depression, anxiety, and low self-esteem, have each been noted to confer increased risk of substance use in individuals with ADHD.^{5,17,25,50,51} These findings suggest that diagnosing and treating co-occurring conditions in individuals with ADHD may help to reduce the risk of developing SUDs.

STIMULANT MEDICATIONS

Stimulant medications are highly effective for children and adolescents in reducing the core symptoms of ADHD.⁵² The most commonly used preparations of stimulant medication are methylphenidate and amphetamine. Atomoxetine, a selective norepinephrine reuptake inhibitor, and long-acting guanfacine and clonidine, which are selective α_2 -adrenergic agonists, are also recommended for the management of some ADHD symptoms.⁴ However, the effect sizes (meaning likelihood of reducing ADHD symptoms compared with placebo) are lower for atomoxetine and long-acting guanfacine and clonidine than they are for the stimulant medications.

Stimulant medications are both more effective at treating ADHD symptoms⁵³ and much more commonly misused than nonstimulant medications. Pediatricians are thus in a position to prescribe a medication that can reduce both ADHD symptoms and the risk of developing an SUD and simultaneously pose a risk for abuse and diversion. An understanding of the factors associated with misuse, abuse, and diversion of stimulant medication may help to guide safe use. Table 1 lists the most commonly

used medications for ADHD and their suspected relative abuse potential.

The terms "misuse," "diversion," and "abuse" are all associated with improper use of medication, but they are different phenomena with different definitions. The term misuse includes the use of medications not prescribed to the individual and using medications in ways other than prescribed. Examples of misuse include taking larger or more frequent doses than prescribed or using someone else's medication to enhance performance.¹³ The most common reasons reported for stimulant misuse are to concentrate, study, and improve grades; "to party" and "get high"; and to experiment.^{54–57} Most individuals who misuse stimulant medications do so via oral administration, with intranasal insufflation ("snorting") less common.^{43,46} Adolescents who report snorting medications or using stimulants to "get high" may be at highest risk of stimulant abuse and dependence.⁵⁸ The term diversion means the transfer of medication from the person to whom it is prescribed to a person for whom it is not prescribed.¹³ The term substance abuse was used in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, to refer to use associated with problems or risk that interfere with functioning. The term addiction refers to loss of control or compulsive use of a substance. In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), diagnostic terms were changed to SUD, mild/moderate/severe, depending on the number of positive criteria.³ Even though they are not formal diagnoses, the terms substance abuse and addiction will likely remain in the lexicon and retain their meaning for some time, particularly in reference to prescription medications.

TABLE 1 List of Most Commonly Used Medications for ADHD With Suspected Relative Abuse Potential

Stimulant Status	Medication Type	US Trade Name ^a	Suspected Relative Abuse Potential ^b	
Stimulants				
Short-acting/immediate release	Methylphenidate	Ritalin ^a	High	
		Methylin ^a	High	
		Dexmethylphenidate	High	
		Amphetamine-dextroamphetamine	High	
		Dextroamphetamine	Dexedrine	High
			DextroStat ^a	High
	LA/ER	Methylphenidate	ProCentra	High
			Metadate CD	Medium
			Metadate ER ^a	Medium
			Ritalin LA ^a	Medium
			Ritalin SR ^a	Medium
			Methylin ER	Medium
			Daytrana patch	Low
			Concerta ^a	Low
Dexmethylphenidate	Quillivant XR	Low		
	Focalin XR	Low		
	Dextroamphetamine	Dexedrine Spansule ^a	Medium	
	Amphetamine-dextroamphetamine	Adderall XR ^a	Medium	
	Lisdexamfetamine	Vyvanse	Low	
Nonstimulants				
α_2 -adrenergic agonists	Guanfacine	Intuniv	Low	
	Clonidine	Kapvay	Low	
Selective norepinephrine reuptake inhibitor	Atomoxetine	Strattera	Low	

CR, controlled release; ER, extended release; LA, long acting; XR, extended release; SR, sustained release.

^a Indicates that generic formulation is available.

^b Relative abuse potential is suspected based on length of action and formulation of medication.

Misuse of Stimulant Medications

Misuse and diversion of stimulant medications are more widespread problems than abuse or addiction.⁵⁹ Wilens et al⁵⁴ conducted a systematic review of the literature examining misuse and diversion of prescription ADHD medications. Of the 21 studies reviewed, rates of past-year non-prescribed stimulant use ranged from 5% to 9% in grade school and high school children and from 5% to 35% in college-aged individuals. In a large public university in the mid-Atlantic region, Arria et al⁵⁵ found that 18% of students who were not prescribed stimulants engaged in nonmedical stimulant use, more than one-quarter (26.7%) of students with diagnosed ADHD reported having used more medications than prescribed, and 15.6% reported using someone else's

prescription stimulants in their lifetime. Nonmedical use of prescription stimulants was associated with previous use of illicit substances as well as alcohol and marijuana dependence.

Diversion of Stimulant Medications

Diversion of stimulant medication is common. Between 16% and 23% of school-aged children reported that they have been approached to sell, give, or trade their prescription stimulant medication.^{60,61} Boys are more likely to divert their stimulant medications than girls.⁶² The most common source of diverted medications is friends and family members.⁶³ More than one-quarter of university students reported that diverted stimulant medications are easy or somewhat easy to obtain.⁵⁶ Individuals with ADHD who have co-occurring SUDs and/or conduct

disorders are more likely to both misuse and divert their stimulant medication,⁶⁴ as are white individuals, members of fraternities and sororities, and students with lower grade-point averages.^{54,65}

Abuse of Stimulant Medications

Methylphenidate and amphetamine both have known abuse potential, although there is little evidence that these drugs are widely abused by the patients to whom they are prescribed,⁵⁹ and evidence for abuse potential among children and adolescents is limited. "Subjective effect" (ie, how much a person likes a drug, achieves euphoria, experiences reinforcement with use) is an important factor considered in determining abuse potential of a substance. Among individuals without ADHD, both methylphenidate and amphetamine produce significant subjective effects; amphetamine is nearly twice as potent as methylphenidate at equivalent doses.⁶⁶ Research performed in the 1970s revealed that stimulants do not reliably produce these subjective effects in individuals with ADHD.⁶⁷ Fredericks and Kollins⁶⁸ found that individuals with ADHD displayed a higher preference for methylphenidate compared with placebo, although other measures of abuse potential, specifically participant-rated effects of methylphenidate on mood, were not elevated. Thus, the preference for methylphenidate may reflect its therapeutic efficacy rather than abuse potential. Most of the studies evaluating abuse potential of stimulant medications used short-acting preparations, and there is evidence that sustained-release and longer acting preparations have decreased abuse potential.^{59,69} Indeed, short-acting medications are more likely to be misused or abused, and amphetamine preparations are misused and abused more frequently than methylphenidate preparations.^{53,70,71}

SAFE STIMULANT-PRESCRIBING PRACTICES

In light of the high risk of SUDs among individuals with ADHD, pediatricians should seek to accurately diagnose ADHD and treat symptoms appropriately. Several precautions may help to reduce stimulant misuse, abuse, and diversion.

Before Prescribing, Confirm a Diagnosis of ADHD

Inattention is multifactorial. Many children or adolescents who are depressed, anxious, neglected, or having academic difficulty because of a learning disorder may present as inattentive. ADHD is a primary disorder of attention. According to the diagnostic criteria for ADHD in the DSM-5,³ ADHD symptoms must be present during childhood; thus, particular caution is warranted before making a new diagnosis of ADHD, especially in an adolescent. Although it is possible that symptoms in childhood were unnoticed, adolescents sometimes attempt to get a stimulant prescription by feigning symptoms of ADHD.⁷² The diagnosis of ADHD is made clinically in an individual who fulfills the criteria for ADHD listed in the DSM-5.³ Standardized tools, such as parent- and teacher-completed ADHD rating scales, assist in making a diagnosis and should be used in the assessment.⁷³ A thorough history, review of medical and school records, and a collateral parent interview may all help confirm a correct diagnosis. The criteria used for diagnosing ADHD and any history or evaluations that were made to rule out other conditions that might be confused with ADHD (eg, sleep disturbances, other learning disabilities, thyroid dysfunction) should be recorded in the patient's medical record. The AAP's Clinical Practice Guideline for ADHD provides specific guidance about diagnosis and management.⁴

Screen Older Children and Adolescents for Use of Alcohol, Marijuana, and Other Drugs

The AAP recommends screening, brief intervention, and referral to treatment as part of routine health care for older children and adolescents.⁷⁴ This recommendation is particularly important for adolescents with ADHD, who are more likely to use substances and to develop an SUD than their peers. Adolescents with ADHD who use alcohol, marijuana, or other substances are also more likely to divert stimulant medication and thus require increased attention and monitoring by their prescriber.

The AAP policy statement titled "Substance Use: Screening, Brief Intervention, and Referral to Treatment for Pediatricians"⁷⁴ provides a complete review of recommended screening tools and brief interventions for adolescent substance use. The AAP currently recommends the 3 "opening questions" associated with the CRAFFT tool (see the following text) to detect past-year substance use. Although currently an active area of National Institutes of Health-funded research,^{75,76} these questions have not been validated to date, and it is not known whether the "other drugs" question is sensitive enough for identifying misuse or abuse of prescription medications. An additional question (eg, "Have you ever used someone else's prescribed medication?") may be warranted to identify misuse, particularly before prescribing a stimulant medication for the first time.

"Opening questions" to identify past-year substance use:

In the past year, have you:

1. Had a drink with alcohol in it?
2. Used marijuana?
3. Used any other substance to get high?

Provide Anticipatory Guidance

Anticipatory guidance regarding proper use of stimulant medications should be part of every patient encounter in which medications for ADHD are discussed. Table 2 lists points that should be included in this discussion. The pediatrician should discuss that medications should only be taken as prescribed by the physician, even with very young children, in a developmentally appropriate manner. As children enter the upper elementary school years, the conversation should evolve to include discussion about the proper use of medication. Children and parents should be aware of the risk for misuse, diversion, and abuse. Children should understand that trading or selling stimulant medication is illegal. Children who live in areas of high-crime rates should have a concrete, realistic safety plan for managing their medication. For children who are 12 years and older, the discussion should also include information about careful transitioning of administration of medication. Although the child should not be pushed to start self-administering medication, having this discussion earlier with the family can alert them that transition of medication management from caregiver to child should be a gradual and carefully monitored one so that when the child is developmentally ready to assume more responsibility of medication management, there is a plan in place to ensure that the transition is safe.

Document Prescription Records

Stimulant medication is a Drug Enforcement Administration Class II controlled substance. Every prescriber must document and monitor the prescribing of stimulant medications. Requests for early refills should be explored and carefully documented to

TABLE 2 Discussion Points for Anticipatory Guidance Regarding Stimulants and Substance Use**Proper administration**

At each clinic visit, review with the patient how he or she is taking his or her stimulant medication.

- Only take the amount of medicine prescribed. Do not take extra medication.
- Take your stimulant medication exactly as prescribed. Do not change the dose or timing. Speak to your doctor if you do not think your medication is working as it should or if you are experiencing adverse effects.
- Do not use alcohol, tobacco, marijuana, or other illicit substances. Drug use worsens problems with attention, leads to medication noncompliance, and can interact with stimulant medication.
- If stimulant medication is administered at school, it should be dispensed at school nurse's office or other safe location with adult supervision.

Risk of misuse, diversion, and abuse

For people who do have ADHD, when stimulant medications are taken as prescribed, there is no increased risk of abuse; rather, stimulant medication appears to decrease the risk of developing an SUD.

- Explain that some people who do not have ADHD may take stimulant medications inappropriately.
- Inform patient and parent that children and adolescents may be asked to give away or sell their stimulant medications but should never do so. Parents may role play appropriate responses so that the child will be prepared if asked. Have the patient and parents keep medication in a safe location (either at home or in a locked office at school). Medications should never be carried in a backpack or purse.

Transition of care

Transitioning of administration of stimulant medication from caregiver to child/adolescent should be done incrementally. Parents and patients should be counseled that ADHD generally persists into adulthood.

- To start a transition, the child/adolescent must be able to remember to take medication as prescribed. Signs suggesting readiness should include the ability to name the medication, dose, and timing of administration as well as emerging signs of independence in other areas, such as being home alone, carrying a key, completing homework independently, or participating in care for a pet.
- The caregiver should continue to periodically supervise medication administration and monitor the child's/adolescent's overall school, social, and family functioning. Weekly pill dispensers can allow burgeoning autonomy for the child/adolescent while allowing the caregiver to monitor doses and control the supply.
- If concerns develop regarding medication misuse or diversion or use of other drugs, the parent should resume control of the medication, dispense each dose, and monitor carefully.

detect a pattern of frequent early requests. Similarly, it is important to document communications between multiple providers who share responsibilities for prescribing medications or altering treatment regimens for the same patient.

Prescribing Medications for ADHD in Context of Active SUD

Illicit substance use often results in attention difficulties, hyperactivity, and/or impulsivity, making a new diagnosis of ADHD difficult or impossible to distinguish from symptoms related to ongoing substance use. In these cases, reevaluation after a period of abstinence may be warranted.

Adolescents who have both previously diagnosed ADHD and an active SUD may be difficult to monitor because

symptoms of substance use may be indistinguishable from ADHD symptoms. In general, an active SUD should be treated (usually via referral to a mental health counselor or addiction specialist) before beginning medication to treat ADHD. However, for patients with well-documented ADHD that predates the onset of substance use, it may be reasonable to treat both disorders concurrently. Consultation with a psychiatrist or addiction specialist when managing complex patients is suggested.

When considering which ADHD medication to prescribe to a patient with a co-occurring SUD, a careful risk/benefit assessment must be conducted. If the patient is currently abusing prescription stimulants or there is a clear indication that the patient would sell or divert stimulant

medication, it may be best to start with a long-acting stimulant medication with low risk of misuse or diversion. Long-acting preparations, especially those with an osmotic controlled-release oral delivery system such as Concerta, have lesser likelihood of misuse or diversion.⁷⁷ It is also reasonable to consider use of a non-stimulant preparation,⁷⁸ even though nonstimulant medications are less efficacious than stimulants.⁷⁹ The prodrug formulation of dextroamphetamine, lisdexamfetamine, has a lower abuse potential than other stimulants and thus may be considered.^{80,81} However, physicians should be aware that any psychoactive medication can be misused. As for all patients, it is important to carefully monitor medication adherence.

A special circumstance occurs when a pediatrician prescribes stimulant medications for college students and older patients living away from home. A treatment plan should document how medication will be prescribed and how frequently the patient is expected to return for follow-up visits with the pediatrician. Medication administration by a student health staff member or keeping medications in a small medication safe may reduce diversion or theft. Follow-up visits should include self-report of medication efficacy, adverse effects (appetite, abdominal symptoms, headaches, and sleep disturbance) and screening for medication misuse, abuse, or diversion. The patient's responses should be documented in the medical record. Reports or suggestions of new physical or mental health symptoms require reevaluation.

SUMMARY

ADHD is a common neurobehavioral disorder of childhood, and individuals with ADHD are more likely to misuse alcohol, tobacco, and other illicit

substances compared with children and adolescents without ADHD. Individuals with ADHD and co-occurring mental health conditions, such as disruptive behavior disorders or depression, are at even higher risk of developing SUDs. Appropriate treatment of ADHD symptoms with medication and behavior therapy may reduce the risk of development of SUDs. Primary care providers should seek to identify and treat ADHD to prevent the development of SUDs. However, the recommended first-line medication therapy for ADHD is stimulant medications, which themselves pose a risk of misuse, diversion, and abuse. Therefore, an important part of ADHD treatment and stimulant medication management

includes screening for SUDs and providing anticipatory guidance around the appropriate and safe use of stimulant medications. Individuals with co-occurring ADHD and active SUDs require a careful, individual risk/benefit assessment regarding the safety of prescribing a stimulant medication. Longer acting preparations of stimulant medication, the prodrug formulation of dextroamphetamine, and non-stimulant medications for ADHD all have lower abuse potential than short-acting preparations of stimulant medication and, thus, their use should be strongly considered if there is a high risk of misuse, diversion, or abuse of stimulant medications.

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Child Life Services

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- *Policy Statement*

POLICY STATEMENT

Child Life Services

COMMITTEE ON HOSPITAL CARE and CHILD LIFE COUNCIL

KEY WORDS

child life, play, patient- and family-centered care, preparation, psychological preparation, therapeutic play

ABBREVIATIONS

CCLS—certified child life specialist

ED—emergency department

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abstract

FREE

Child life programs are an important component of pediatric hospital-based care to address the psychosocial concerns that accompany hospitalization and other health care experiences. Child life specialists focus on the optimal development and well-being of infants, children, adolescents, and young adults while promoting coping skills and minimizing the adverse effects of hospitalization, health care, and/or other potentially stressful experiences. Using therapeutic play, expressive modalities, and psychological preparation as primary tools, in collaboration with the entire health care team and family, child life interventions facilitate coping and adjustment at times and under circumstances that might otherwise prove overwhelming for the child. Play and developmentally appropriate communication are used to: (1) promote optimal development; (2) educate children and families about health conditions; (3) prepare children and families for medical events or procedures; (4) plan and rehearse useful coping and pain management strategies; (5) help children work through feelings about past or impending experiences; and (6) establish therapeutic relationships with patients, siblings, and parents to support family involvement in each child's care. *Pediatrics* 2014;133:e1471–e1478

CHILD LIFE PROGRAMS

During the 1920s and 1930s, early hospital play programs were initiated at several children's hospitals, including Mott Children's Hospital, Babies and Children's Hospital of Columbia Presbyterian, and Montreal Children's Hospital. In 1955, Emma Plank, under the direction of Dr Frederick C. Robbins (Nobel Laureate), developed the first Child Life and Education division at Cleveland City Hospital. Plank is considered a founding "mother" of the profession, and her landmark publication, *Working With Children in Hospitals*,¹ served to educate many about the unique needs of children in the health care setting.

Today, hospitals specializing in pediatric care routinely include child life programs, with more than 400 programs in operation in North America.² Child life services are recommended and offered to varying degrees in community hospitals with pediatric units, ambulatory clinics, emergency departments (EDs), hospice and palliative care programs, camps for children with chronic illness, rehabilitation settings, and some dental and physician offices.^{3–7} In cases of hospitalized or ill adults, certified child life specialists (CCLSs) may be consulted to work with children of adult patients, particularly in end-of-life cases, trauma, and critical care. Child life programs are not

unique to North America; similar programs can be found in other countries such as the United Kingdom, Japan, Kuwait, the Philippines, South Africa, Serbia, New Zealand, and Australia.²

The provision of child life services is a quality benchmark of an integrated patient- and family-centered health care system, a recommended component of medical education, and an indicator of excellence in pediatric care.^{8–10} An experimental evaluation of 1 child life program model showed that child life interventions resulted in less emotional distress, better overall coping during the hospital stay, a clearer understanding of procedures, and a more positive physical recovery as well as posthospital adjustment for children enrolled.¹¹ Patients spent less time on narcotics, the length of stay was slightly reduced, and parents were more satisfied. Other studies have found that child life interventions play a major role in calming children's fears and result in higher parent satisfaction ratings of the entire care experience.^{12,13}

There are a number of variables to consider in identifying adequate child life staff-to-patient ratios. Although a ratio of 1 full-time CCLS to 15 inpatients¹⁴ is useful as a guideline, a number of factors should influence specific staffing allocations. Generally speaking, child life services should be available to meet identified patient or family needs 7 days a week. In hospitals with very small pediatric units and low outpatient volume, 1 CCLS may provide services in both the inpatient and outpatient areas, including consultation services to the ED. In hospitals with high-volume pediatric emergency services, more than 1 CCLS is generally required to enable 7-day coverage of the ED. In larger hospitals, 1 or more CCLSs are typically assigned to each inpatient unit or outpatient area, including standing and/or rotating schedules to provide weekday, evening, and week-

end coverage. In any case, staffing plans should be sufficient to meet fluctuations in anticipated and unanticipated staff absences, seasonal swings in patient census, and nonclinical community activities (eg, increased visits and in-kind donations during the holiday season, variations in individual patient and family needs).

Child variables (temperament, coping style, and cognitive abilities), family variables (parental anxiety, presence, and involvement), and diagnosis/treatment variables (the number of invasive procedures) are known to affect psychosocial vulnerability and thus influence the child's particular child life intervention needs.¹⁵ A combination of psychosocial risk assessment, medical/treatment variables (eg, the proportion of patients with isolation precautions, the volume of patient/family teaching needs), and the time requirements associated with particular interventions directly affect operational staff-to-patient ratios in both inpatient and outpatient settings.^{16,17} Table 1 lists variables that typically require child life interventions of greater frequency, duration, or complexity, thus influencing effective CCLS-to-patient ratios.

The credentials of a CCLS currently include the minimum of a bachelor's degree in child life, child development, or a closely related field; the successful completion of a 480- to 600-hour child life internship under the supervision of a CCLS; and passing a standardized certification examination.^{18,19} Advanced degrees in child life

are also available, and CCLSs often develop particular areas of expertise related to the patient populations they serve.

In some settings, child life services are augmented by child life assistants (or activity coordinators or child life technicians). Child life assistants are typically required to have core college coursework, such as an associate's degree in child development, and experience with children in group settings. They generally focus on the "normalization" of the health care experience, providing play activities, coordinating special events (eg, community visitors, holiday celebrations), and maintaining the playroom environment. Both CCLSs and child life assistants actively participate in the orientation, training, and supervision of volunteers, thereby contributing to volunteer effectiveness, satisfaction, and retention. This collaboration enables the CCLS to conduct an assessment and delegate as appropriate, allowing patients with varying degrees of psychosocial vulnerability and activity levels to be supported by the team member whose skills and knowledge are most closely aligned with patient/family needs. Although volunteers are a valuable supplement, they can never be considered an adequate replacement for trained/certified professionals.

CCLSs are part of an interdisciplinary, patient- and family-centered model of care, collaborating with the family, physicians, advance practice providers, nurses, social workers, and

TABLE 1 Factors Necessitating or Supporting a Lower Ratio of Patients to CCLSs

- High volume of patient-family teaching needs (eg, surgeries and other medical procedures), especially when combined with high patient turnover rate
- High proportion of patients requiring 1-on-1 interventions (eg, isolation rooms, ventilator-dependent patients, examination/treatment room interventions, critical care units)
- Multiple simultaneous needs (eg, ED during peak hours)
- Frequent time-consuming demands (eg, support during lengthy medical procedures, end-of-life support)
- Significant nonclinical demands, such as supervision of child life students, representing child life on hospital committees, public relations and marketing activities, and other administrative duties

other members of the health care team to develop a comprehensive plan of care. Child life contributions to this plan are based on the patient's and family's psychosocial needs, cultural heritage, and responses to the health care experience. For example, child life specialists can participate in the care plan by teaching a child coping strategies for adjusting to a life-changing injury, promoting coping with examinations for alleged abuse, assisting families in talking to their children about death, facilitating nonpharmacologic pain management techniques, and communicating the child's developmental and individual needs and perspective to others. These interventions are most effective when delivered in collaboration with the entire health care team.

THE THERAPEUTIC VALUE OF PLAY

Play is an essential component of a child life program and of the child life professional's role. In addition to play's developmentally supportive benefits and as a normalizing activity for children and youth of all ages, it is particularly valuable for children who are anxious or struggling to cope with stressful circumstances.²⁰ Erikson writes, "To play out is the most natural auto-therapeutic measure childhood affords. Whatever other roles play may have in the child's development . . . the child uses it to make up for defeats, sufferings, and frustrations."²¹

Play in the health care setting is adapted to address unique needs based on developmental level, self-directed interests, medical condition and physical abilities, psychosocial vulnerabilities, and setting (eg, bedside, playroom, clinic). Play as a therapeutic modality, including health care play or "medical play," has been found to reduce children's emotional distress and help them cope with medical experiences.²² Research has shown that physiologic

responses, such as palm sweating, excessive body movement, tachycardia, and hypertension, can be reduced with therapeutic play interventions.²³

Play can be adapted to address the developmental and psychosocial needs of patients in every pediatric age group. For example, infants and toddlers benefit from exploratory and sensorimotor play, and preschool-aged children enjoy fantasy play and creative art activities.²⁴ Opportunities for parents to engage in play activities with their young children are beneficial to both patient and family, alleviating some feelings of helplessness in parents and assisting in the child's hospital adjustment.²⁵ School-aged children and adolescents seek play that contributes to feelings of mastery and achievement, which is one reason video games are so popular with this age group.²⁶ Patients in this age group also benefit from activities that allow them to maintain relationships with peers and establish new connections through, for example, online networking and the availability of teen activity rooms in the hospital setting.²⁷

Auxiliary programs, such as animal-assisted therapy, infant massage instruction, use of therapeutic clowns, performing arts, and artist-in-residence programs, often used in conjunction with child life services, provide additional outlets for patients of all ages and their families.^{28,29} Live, interactive programming, such as hospital bingo or patient-produced videos (broadcast over a closed-circuit television system), can be a particularly effective way to engage patients restricted to their rooms for infection control or medical reasons. Expressive therapies, such as those provided by distinctly certified play therapists, music therapists, and art therapists, can be offered to complement child life programs and to provide support for particularly vulnerable patients.^{30,31}

PSYCHOLOGICAL PREPARATION

Preparing children for hospitalization, clinic visits, surgeries, and diagnostic/therapeutic procedures is another important element of a child life program. It is estimated that 50% to 75% of children develop significant fear and anxiety before surgery, with recognized risk factors such as age, temperament, baseline anxiety, past medical encounters, and parents' level of anxiety.³² Children's anxiety in the peri-operative environment is associated with impaired postoperative behavioral and clinical recovery, including increased analgesic requirements and delayed discharge from the recovery room.³³ More than 50 years of research and experience support 3 key elements of the preparation process: (1) the provision of developmentally appropriate information; (2) the encouragement of questions and emotional expression; and (3) the formation of a trusting relationship with a health care professional.³⁴ A recent systematic review of preparation effectiveness evidence concluded that children who were psychologically prepared for surgery experienced fewer negative symptoms than did children who did not receive formal preparation. In addition to reducing anxiety and providing a more positive experience for the patient and family, research demonstrates that preparation and coping facilitation interventions decrease the need for sedation in procedures such as MRIs, resulting in lower risks for the child and cost savings in personnel, anesthesia, and throughput-related expenses.^{35–37}

Preparation techniques, materials, and language must be adapted to the developmental level, personality, and unique experiences of the child and his or her family. Learning is enhanced with "hands-on" methods versus exclusively verbal explanations. Photographs, diagrams, tours of surgical or

treatment areas, actual and pretend medical equipment, and various models (eg, dolls, puppets) are used to reinforce learning and actively engage the child.^{32,38} Interpreter services are used as appropriate to ensure understanding in patients or families who do not speak English or for whom English is a second language. Most parents have a strong desire for comprehensive information about their child's care and should be included in the preparation process. In cases in which children demonstrate avoidant preferences or when preparation before the event is not possible, the CCLS's focus may change from that of imparting information to other supportive strategies, such as teaching behavioral coping skills and preparing parents to support their child during a medical procedure.

PAIN MANAGEMENT AND COPING STRATEGIES

When combined with preparation and appropriate pharmacologic interventions, nonpharmacologic strategies for pain and distress management have proven successful in terms of patient/family experience, staff experience, and cost-effectiveness.^{13,39–40} Strategies such as swaddling, oral sucrose, vibratory stimulation, breathing techniques, distraction, and visual imagery have been shown to decrease behavioral distress and pain experience in children during invasive medical procedures.^{41–43} In addition to advocating for the appropriate use of analgesics, CCLSs are often directly involved in the utilization of nonpharmacologic pain management techniques and coaching or supporting patients and families before and/or during distressing medical procedures.^{44,45} They can also provide valuable education and training to nursing, medical, and other personnel and students, thus supporting health care team member competencies in the

provision of developmentally appropriate, psychosocially sound care.^{46,47} Multifaceted institution-wide protocols such as the “Ouchless Place” and other similar programs incorporate the standard utilization of both pharmacologic and nonpharmacologic techniques, preparation of patient and family, environmental considerations, and training of all health care team members.^{48,49} Research has demonstrated that children are less fearful and distressed when positioned for medical procedures in a sitting position, rather than supine.⁵⁰ CCLSs are often involved in facilitating the use of “comfort holds”: techniques for positioning children in a parent/caregiver's lap or other comforting position. In addition to reducing the child's distress and gaining his or her cooperation, these techniques generally require fewer staff to be present in the room, facilitate safe and effective accomplishment of the medical procedure, decrease parent anxiety, and increase parent satisfaction.^{51–53} With a goal to limit the use of papoose boards and alleviate the practice of multiple staff members holding a child down, these techniques provide a viable and more humane alternative in most cases.

CCLSs may also develop “comfort kits” for use in treatment areas to include age-appropriate distraction items such as bubbles, pop-up and sound books, light-up toys, and other visual or auditory tools.⁵⁴ There is emerging evidence that mobile devices can be effective in minimizing patient perceptions of pain and anxiety during distressing medical procedures.⁵⁵ CCLSs can also advocate for a more welcoming environment in treatment and examination rooms on pediatric units as well as outpatient settings. Their background and training are helpful in designing settings that are appropriately stimulating, nonthreatening, and interactive.

FAMILY SUPPORT

The presence and participation of family members is a fundamental component of patient- and family-centered care and has a significant positive effect on a child's adjustment to the health care experience.⁵⁶ When parents or other family members are highly anxious about the child's illness or diagnostic and treatment regimens, such anxiety is easily transmitted to the patient.⁵⁷ CCLSs help facilitate the family's adjustment to the child's illness and health care experience. They can help family members understand their child's response to treatment and support caregiving roles by promoting parent/child play sessions and sharing strategies for comforting or coaching the child during medical procedures.

Siblings of pediatric patients present with their own unique anxieties and psychosocial needs, needs that are often not assessed or addressed. Siblings, much like children of adult patients, can be helped to comprehend a family member's illness via therapeutic play and educational interventions or by offering support during hospital visits, including critical care and end-of-life situations.⁵⁸ CCLSs are often involved in providing grief support or legacy activities, such as hand molds or memory boxes for siblings and other family members in the event of the death of pediatric or adult patients.

RECENT DEVELOPMENTS IN CHILD LIFE SERVICES

The scope of child life programs has developed beyond pediatric inpatient medical–surgical settings to include outpatient and other areas in which child life expertise can be effectively applied to support children and families in stressful situations. The provision or expansion of dedicated child life programming in areas such as emergency services, surgery, imaging, specialty care clinics, dialysis centers,

palliative care, and neonatal intensive care has become more prevalent.^{59,60} The increase in patients diagnosed with autism spectrum disorders has presented opportunities for child life specialization in supporting this population in the medical setting.⁶¹

Over the past several years, child life programs have adapted to the great variety of patients and illnesses seen in pediatrics. Younger, less mobile patients who have more complex medical conditions may need greater individualization of care from the CCLS, for example, when group interaction is not possible. Activities that enable social interaction, such as Internet connectivity and closed-circuit television programming, are particularly helpful for patients who are isolated for infection control or confined for monitoring reasons. Given the increasing survival rate of patients with cystic fibrosis, cardiac conditions, and other chronic illnesses, more teenagers and young adults face the challenging transition to adult health care.⁶² Acknowledging team goals to normalize the transition process and address patient and family anxieties or questions, CCLSs can assist in this transition by providing education and helping patients to communicate their needs, fears, hopes, and expectations.^{63–65}

Although evidence supports the value of child life programs, financial pressures in many health care settings have threatened the growth and sustainability of this essential service. Recent literature has demonstrated the benefits of child life interventions in reducing sedation-related costs,³⁵ and additional research is underway to further evaluate the cost-effectiveness of child life services.

Child life programs are recognized as contributing to a culture of patient- and family-centered care as well as to customer satisfaction measures, increasingly important from an incentive-

based reimbursement and accreditation standpoint as well as marketing and public reporting of outcomes. Child life and ancillary services, such as creative arts therapy, often attract a segment of the population that may otherwise not be inclined to provide philanthropic support to a hospital. Child life leaders are regularly involved in community outreach, public relations, and funding of development activities.

ADDITIONAL CONSIDERATIONS

Child life services contribute to an organization's efforts to meet the standards set forth by The Joint Commission with regard to effective communication, patient- and family-centered care, age-specific competencies, and cultural competence.⁶⁶ The CCLSs' psychosocial and developmental expertise and their keen awareness of the benefits of patient- and family-centered care provide a useful perspective at the systems level. Child life representation is often incorporated into hospital committees, such as ethics, patient/family satisfaction, safety, environmental design, and bereavement. In many cases, child life professionals provide leadership for activities such as patient and/or family advisory councils and hospital-wide staff education.

Child life expertise has applications beyond conventional hospital care. Interventions can help children transition back to their home, school, community, and medical home.*⁶⁷

*The American Academy of Pediatrics (AAP) believes that the medical care of infants, children, and adolescents ideally should be accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally effective. It should be delivered or directed by well-trained physicians who provide primary care and help to manage and facilitate essentially all aspects of pediatric care. The physician should be known to the child and family and should be able to develop a partnership of mutual responsibility and trust with him or her. These characteristics define the "medical home."

CCLSs often collaborate with local school districts to arrange hospital or homebound education, and hospital-based teachers may be incorporated into child life program administration.

For hospitals or other health care settings considering the initiation or expansion of child life services, the Child Life Council offers a consultation service to support existing program review and development, new program start-up, interdisciplinary education, and written standards of care.⁶⁸ In community hospital settings with few pediatric beds and minimal pediatric outpatient or ED visits, the provision of full-time child life services may not be financially feasible. In such cases, it is recommended that part-time or consultative services of a CCLS be obtained to assist in the ongoing education of staff, students, and volunteers as well as to advise on a psychosocially sound, developmentally appropriate, patient- and family-centered approach to care.

CONCLUSIONS

Child life services improve quality and outcomes in pediatric care as well as the patient and family experience. Although more research is needed, there is evidence that child life services help to contain costs by reducing the length of stay and decreasing the need for sedation and analgesics. Patient/family satisfaction data and interdisciplinary team member feedback further confirm the positive effects of child life programs on children, families, and staff. It remains essential for child life services to adapt and grow with the changing health care delivery system in support of the highest possible quality of care for children and their families.

RECOMMENDATIONS

1. Child life services should be delivered as part of an integrated patient- and family-centered model of

care and included as a quality indicator in the delivery of services for children and families in health care settings.

2. Child life services should be provided directly by certified child life specialists in pediatric inpatient units, emergency departments, chronic care centers, and other diagnostic/treatment areas to the extent appropriate for the population served. In hospitals with a small number of inpatient or outpatient pediatric visits, ongoing consultation with a certified child life specialist is recommended to educate health care team members and support developmentally appropriate, patient- and family-centered practice.
3. Child life services staffing should be individualized to address the needs of specific inpatient and outpatient areas. Child life specialist-

to-patient ratios should be adjusted as needed for the medical complexity of patients served, including psychosocial and developmental vulnerability as well as family needs and preferences.

4. Child life services should be included in the hospital operating budget as an essential part of hospital-based pediatric care. Advocacy for financing of child life services should occur at the facility, community, state, and federal levels.
5. Additional research should be conducted to evaluate the effects of child life services on patient care outcomes, including patient and family experience/satisfaction, staffing ratios, throughput, and cost-effectiveness.

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Children's Health Insurance Program (CHIP): Accomplishments, Challenges, and Policy Recommendations

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- *Policy Statement*

POLICY STATEMENT

Children's Health Insurance Program (CHIP): Accomplishments, Challenges, and Policy Recommendations

abstract

FREE

Sixteen years ago, the 105th Congress, responding to the needs of 10 million children in the United States who lacked health insurance, created the State Children's Health Insurance Program (SCHIP) as part of the Balanced Budget Act of 1997. Enacted as Title XXI of the Social Security Act, the Children's Health Insurance Program (CHIP; or SCHIP as it has been known at some points) provided states with federal assistance to create programs specifically designed for children from families with incomes that exceeded Medicaid thresholds but that were insufficient to enable them to afford private health insurance. Congress provided \$40 billion in block grants over 10 years for states to expand their existing Medicaid programs to cover the intended populations, to erect new stand-alone SCHIP programs for these children, or to effect some combination of both options. Congress reauthorized CHIP once in 2009 under the Children's Health Insurance Program Reauthorization Act and extended its life further within provisions of the Patient Protection and Affordable Care Act of 2010. The purpose of this statement is to review the features of CHIP as it has evolved over the 16 years of its existence; to summarize what is known about the effects that the program has had on coverage, access, health status, and disparities among participants; to identify challenges that remain with respect to insuring this group of vulnerable children, including the impact that provisions of the new Affordable Care Act will have on the issue of health insurance coverage for near-poor children after 2015; and to offer recommendations on how to expand and strengthen the national commitment to provide health insurance to all children regardless of means. *Pediatrics* 2014;133:e784–e793

LEGISLATIVE BACKGROUND AND EVOLUTION OF THE CHILDREN'S HEALTH INSURANCE PROGRAM

The Children's Health Insurance Program (CHIP) emerged as a consequence of previous policy experiences and political realities that characterized the late 1990s. The combination of successful Medicaid expansions in the late 1980s and early 1990s and the failure of the Clinton health reform proposals of the mid-1990s prepared the stage for both Democrats and Republicans to cooperate in fashioning an extension of health insurance for 10.1 million uninsured near-poor

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KEY WORDS

Children's Health Insurance Program, CHIP, Affordable Care Act, health insurance, pediatrics

ABBREVIATIONS

AAP—American Academy of Pediatrics
ACA—Patient Protection and Affordable Care Act
CHIP—Children's Health Insurance Program
CHIPRA—The Children's Health Insurance Program Reauthorization Act of 2009

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children that would not establish a new entitlement program.¹ The resulting legislation, Title XXI of the Social Security Act (42 USC 7, §§1397aa–1397mm), inserted a provision into the Balanced Budget Act of 1997 (Pub L No. 105–33, 111 Stat 251) that encouraged states to establish programs to provide health insurance to noncovered children who lived in families with incomes up to 200% of the federal poverty level. The act incorporated specific design elements that made it more attractive to state governments, which would bear a large responsibility for its implementation. Using a level of federal matching funds in excess of that provided to the Medicaid program (70% of the cost of the program, on average, compared with 57% for Medicaid),² states were enabled to craft programs that were either extensions of their existing Medicaid programs or new stand-alone programs or a combination of both.³ The stand-alone programs were permitted to include cost sharing and premiums, and their benefit packages could differ from what was available in Medicaid, whereas the Medicaid extension programs were required to adhere to the traditional Medicaid package.

The new legislation budgeted \$40 billion for the 10 years of the program as a capped block grant to states rather than as an entitlement. To prevent states from shifting children from Medicaid to a program with greater federal cost sharing, the law mandated a maintenance-of-effort obligation and strict screening of Medicaid eligibility. To discourage crowd-out from the commercial insurance pool, the law also limited availability of the program to individuals without other forms of potential coverage and imposed waiting periods before patients could access the program after losing private coverage.⁴

As states were establishing their programs in the early years of CHIP, the

federal allotments exceeded state expenditures. By 2000, however, every state and territory as well as the District of Columbia had established its own program, so that by the middle part of that decade, states were beginning to find that their expenditures were outstripping the federal block grants allocated to them. To remedy such shortfalls in 2006 and again in 2007, Congress appropriated increased funds for the program above the original 1997 allocation.

At the 10-year mark, despite considerable progress in coverage for near-poor children, CHIP continued to confront 3 issues: provision of sufficient financing for the states to meet the needs of the intended population; adequate outreach, enrollment, and retention efforts for eligible children; and a perceived need to focus more on access and the quality of care for those covered.⁵ The 110th Congress attempted to reauthorize the program in 2007, but despite passage in both houses of Congress, the legislation was twice vetoed.⁶ In the absence of long-term funding, the Medicare, Medicaid, and CHIP Extension Act of 2007 (Pub L No. 110–173) was enacted to appropriate funds at the 2007 level to cover the costs of the program for 2008 through March 31, 2009.⁷

After the 2008 presidential elections, the new administration set the extension of CHIP as an important early legislative priority. President Obama signed the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA; Pub L No. 111-3) into law on February 4, 2009,⁸ with several specific policy goals in mind. The law increased appropriations for the program in acknowledgment of the shortfalls that states had been experiencing under the previous funding levels and extended the life of the program through 2013. In addition, it included a number of funding mechanisms, such as

Express Lane eligibility and state bonuses for reaching enrollment goals that were intended to extend Medicaid and CHIP coverage to millions of additional uninsured children and to increase outreach to many who lacked coverage despite being eligible for these programs. Finally, it improved benefits, enhanced data collection, and created a new emphasis on measuring the quality of care children received.⁹

One year later with the passage of the Patient Protection and Affordable Care Act (ACA; Pub L No. 111–148 [2010]),¹⁰ other modifications of CHIP came online: in particular, the ACA extended the funding for CHIP by another 2 years, through September 31, 2015. In addition, because the ACA enabled all citizens younger than 65 years with household incomes less than 133% of the federal poverty level (\$31 322 for a family of 4 in 2013, to which a 5% income disregard will be applied when considering eligibility)* to become eligible for Medicaid effective January 2014 (if, in view of the June 2012 Supreme Court decision, their state of residence agrees to participate in the Medicaid expansions),¹¹ the ACA anticipated that some children older than 6 years previously covered by a stand-alone CHIP plan would transition into Medicaid. In such cases, the ACA provides states the enhanced CHIP matching rates for those individuals. Furthermore, beginning in fiscal year 2016, the federal CHIP matching rate is slated to increase by 23 percentage points to an average of 93%. Finally,

*To determine income eligibility for Medicaid under the ACA, the statute references an individual's modified adjusted gross income and adds a standard 5% "income disregard," making the effective threshold for eligibility 138% of the federal poverty level. See "Determining Income for Adults Applying for Medicaid and Exchange Coverage Subsidies: How Income Measured With a Prior Tax Return Compares to Current Income at Enrollment" from The Kaiser Family Foundation Focus on Health Reform at <http://www.kff.org/healthreform/upload/8168.pdf>.

although the ACA extended authority for CHIP through 2019 and included maintenance-of-effort requirements for eligibility, identification, and enrollment of children in Medicaid and CHIP through that time period, it provided federal CHIP allotments to finance the program only through fiscal year 2015.¹²

ACCOMPLISHMENTS OF CHIP

Insurance Coverage

Incontrovertible evidence demonstrates that the CHIP program increased insurance coverage to its intended population above what it would have been in the absence of the program (see Fig 1). Although at the time of CHIP's enactment in 1997, states already had, under the existing Medicaid program, the option of expanding coverage for children in families up to 200% of the federal poverty level, only 6 states had availed themselves of this opportunity.¹³ From the enactment of CHIP in 1997 to 2011, enrollment has grown from under 1 million to 5.3 million children.^{14,15} Furthermore, the enactment of CHIPRA has had important spillover effects on the enrollment of eligible children into Medicaid so that the combined impact on the rate of uninsurance among children has been significant.¹⁶

Although the percentage of US children with private employer-sponsored health insurance decreased from 66.2% to 53.0% over this time, the proportion covered by public insurance, including Medicaid or CHIP, increased from 21.4% to 42.0% so that the total percentage of uninsured US children decreased from 13.9% to 6.6% at a time when the uninsurance rates among adults were increasing.^{17,18} Moreover, the reductions in uninsurance were concentrated among the population of children in families at or below 200% of the federal poverty level. The percentage of children covered by employer-sponsored insurance in this group fell from 34.4% to 24.9%, whereas the percentage of those on Medicaid or CHIP increased from 41.3% to 60.4% so that the uninsurance rate among these children decreased from 24.6% to 15.3% over this period.¹⁷ Beyond extending coverage to more children, specific provisions in CHIPRA made it mandatory for stand-alone CHIP programs to include dental coverage for children (section 2103(c)(5))¹⁹ and to cover mental health services and substance abuse services on parity with medical and surgical coverage.

Even subsequent to the 2008 recession, CHIP continues to increase its enrollment, although at a slower rate than

before. Some have speculated that this slowdown is partially attributable to the migration of some children from CHIP to Medicaid as parents have lost employment.¹⁵ How much of the decline in private insurance coverage can be attributable to enrollment in the CHIP program has generated intense debate in the "crowd-out" literature, but a recent review of the evidence noted that only 4 of 22 pertinent studies examined found statistically significant crowd-out effects.²⁰ Among those who did find evidence of crowd-out, the magnitude of the estimates varied widely from 0% to 50% depending upon the underlying assumptions of their statistical model.²¹

Access to Care

For children enrolled in CHIP programs, most researchers, with occasional dissenting voices,²² have found that access to care and utilization of primary and preventive care appear to improve after enrollment.²⁰ Although methodologic challenges abound in trying to arrive at robust estimations in this regard,²³ evaluations conducted in individual states^{24–26} or across combinations of states^{16,27} have found, in general, that enrollees report improvements in having a usual source of care, in completing visits to physicians or dentists, and in having fewer unmet health needs after enrollment. Furthermore, some observers cite evidence indicating that racial/ethnic disparities in access and utilization detectable among new CHIP participants before they enrolled were either eliminated or greatly reduced after enrollment.²⁸ Other researchers have reported that the benefits of CHIP enrollment with respect to reductions in unmet needs are greater for children with chronic health conditions.²⁹ Finally, older children (older than 13 years) from low-income families who had not been eligible for public health insurance coverage before the enactment of CHIP appear to have had disproportionately greater increases in the

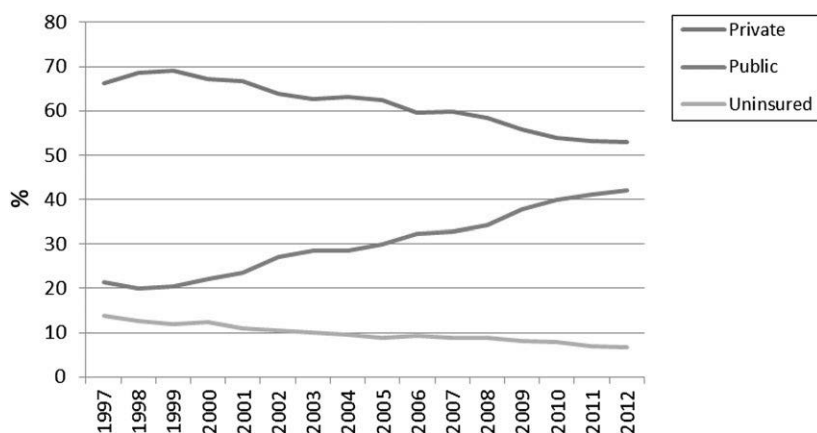


FIGURE 1

Health insurance rates for children in the United States, 1997–2012. Source: National Center for Health Statistics, 2013.¹⁸

likelihood of a physician visit and greater declines in rates of uninsurance as a result of the enactment of this program, when compared with younger children from poor and near-poor households.³⁰

Health Status and Quality of Care

Unambiguous evidence of the effects of CHIP on improvements in children's health status as measured either by mortality rates, morbidity, improved functional status, or parent-reported health assessment is more difficult to substantiate for a variety of reasons.²³ Some of the studies^{31,32} reported benefits of improved publicly funded health insurance lump effects of Medicaid with those of CHIP, even though they apply to different populations and may have been studied in different time periods. Despite these caveats, there are suggestions that enrollment in CHIP may have had positive effects on certain measures of health and well-being among participants.^{33,34}

Finally, over and apart from the direct effects that CHIP has had on the access, utilization, and health status of near-poor children, the provisions in CHIPRA that focus on the quality of care delivered to children are of signal importance. A major innovative element of CHIPRA was the incorporation of quality child health measurement standards, monitoring capabilities, and reporting requirements for states in section 401a of the statute.³⁵ The legislation established a mechanism by which the Centers for Medicare and Medicaid Services collaborated with the Agency for Healthcare Research and Quality to identify an initial core set of child health quality measures on which states could voluntarily agree to report.^{35,36} CHIPRA also allocated a total of \$100 million in awards to 18 states to encourage creation of quality demonstration projects. Since the law's enactment, the US Department of Health

and Human Services has been required to report on the quality of care received by children covered by Medicaid and CHIP.

PROBLEMATIC ISSUES FOR CHIP

CHIP and the ACA

Whereas it is important to acknowledge the signal achievements of the ACA in extending health insurance coverage, reforming practices in the health insurance market, and incentivizing opportunities to moderate health care costs, it is equally necessary to be alert to aspects of the new law that raise concerns regarding the future of CHIP. Many of these concerns emerge only from a detailed understanding of specific features of the legislation and are outlined as follows:

- First and foremost is the question of ongoing funding particularly in view of provisions of the ACA that preserve federal funding for CHIP only through 2015. After this date, it is not certain whether the program will be continued or whether some subset of children currently covered under CHIP who satisfy other eligibility criteria will be expected to transition into the new health insurance marketplaces, whereas others will be left without coverage entirely. This latter scenario may constitute an inferior outcome, even for children who do qualify to be covered by the marketplaces. At least 1 comparative analysis in 17 states found that the benefits and cost-sharing levels in existing CHIP programs were superior to those in the marketplaces.³⁷
- Second, initial experience with federal- and state-sponsored insurance marketplaces suggest that network restrictions limiting access to children's hospitals and certain subspecialists constitute a significant cost-containment strategy in many geographic areas. These restrictions

within the ACA framework are less beneficial to children compared with what they currently experience in CHIP.

- Third, the majority Supreme Court decision upholding the ACA but rendering state participation in the new Medicaid expansions optional¹¹ creates further inconsistencies that might leave certain poor older adolescents ineligible for any public funding in states that refuse to accept the new Medicaid expansions.³⁸ Even if the ACA is implemented such that all states opt to embrace the Medicaid expansions, a considerable number of children will find themselves in situations where their coverage is with a public plan, whereas their parents either have no coverage because they do not qualify for Medicaid under the proposed expansions or have different coverage from their children because they are in one of the marketplace plans, hence complicating coordination of benefits within the family.³⁹
- Fourth, another distinct disadvantage for children under the ACA involves the calculation of eligibility for premium tax credits under the law. The Internal Revenue Service has ruled that those whose premiums cost more than 9.5% of their gross adjusted income are eligible for tax credits from the federal government, but only the cost of an individual policy is taken into account in making this calculation. Because family coverage is more expensive than individual coverage, parents with children may find themselves paying more than 9.5% of their income to obtain coverage but being nevertheless ineligible for these credits (a feature known as the "kid glitch").
- Fifth, although the ACA permits children up to the age of 26 years

to remain on their parents' policies, this benefit does not extend to grandchildren (ie, children who might be born to these young adults).

- Finally, although provisions in the ACA have made redistribution of funds among states more responsive to the differential shortfalls in funding that emerge across different states over time, the block grant nature of the CHIP makes it difficult for all states to adjust their programs to the changing needs and numbers of near-poor children. This situation could become critical if future economic downturns render more families eligible for a program that has a cap on its total spending.

Enrollment and Retention

In addition to the concerns regarding future funding, the current program has yet to address other issues of enrollment and retention. There are now estimated to be 7.7 million children enrolled in the CHIP program, of whom 70% are in stand-alone programs.³ Despite the remarkable success of Medicaid and CHIP at reducing uninsurance among children from low-income families, an estimated 7.5 million children in the United States still remain uninsured, of whom 60% to 70% are thought to be eligible for public insurance of some kind.¹² Identifying those children and increasing the rate at which they enroll in CHIP is an ongoing challenge for the program. For children who do enroll, the rate of retention in the program is also lower than it might be. It was estimated in 2008 that 26.8% of uninsured children had been enrolled in public insurance the previous year, with 21.7% formerly enrolled in Medicaid and 5.1% enrolled in CHIP.⁴⁰ Understanding the reasons for and consequences of these dropouts, whether they result from

barriers associated with state enrollment and reenrollment policies, documentation and related concerns among immigrant parents of children born in the United States, changes in employment status, or other factors, should be a priority for the program.

Part of the advantage of CHIP has been the built-in flexibility it has afforded states with respect to its implementation, particularly among stand-alone CHIP programs rather than pure Medicaid expansions. Because states have faced differential budgetary constraints in the aftermath of the recent recession, having some leeway in how to structure benefits and set eligibility for near-poor children has been a boon to policy makers facing difficult fiscal choices at the state level. This sanctioned flexibility in the rate of CHIP implementation, the degree of cost sharing, the generosity of benefit packages, and the extensiveness of outreach to those eligible but uninsured has, in turn, resulted in considerable state-to-state variation in retention rates and in the overall benefit of the program. Provisions of the ACA will do little to modify these operational aspects of CHIP.

Physician Participation

The rates at which pediatricians have been willing to accept children covered by public health insurance programs have declined in recent years as the payment rates in these programs have generally deteriorated relative to rates associated with commercial plans. A recent report by the Government Accountability Office summarizing a national survey of pediatricians indicated that although 47% of those surveyed reported that they would accept all new Medicaid or CHIP patients, the comparable figure for privately insured patients was 79%.⁴¹ In those states that have CHIP arrangements that are Medicaid expansions (and

some states with a stand-alone CHIP program use Medicaid plans and payment rates in CHIP), rates of acceptance of CHIP patients and Medicaid patients are highly correlated. To attempt to address this concern, at least in part, provisions of the ACA (§1202) require that, for primary care providers, Medicaid payment rates be increased to 100% of those available through Medicare.^{22,42} The federal government has issued a final rule, clarifying the following: (1) that this innovation applies to primary care evaluation and management (E&M) codes 99201–99499, including pediatric services that are not traditionally provided by Medicare practitioners; (2) that they apply to Medicaid managed care plans as well as traditional fee-for-service arrangements; and (3) that they apply to services administered by or under the direction of physicians in primary care specialties or subspecialties.⁴³ This ruling is important especially because three-quarters of CHIP patients are enrolled in managed care plans³ and the payment rates for participation in these plans vary considerably on a regional basis. Most pediatricians are in a disadvantageous position when it comes to negotiating payment rates with large insurance companies that can be the sole payers in a specific geographic locale. Less encouraging is the fact that the increase in the Medicaid fee structure to achieve parity with Medicare is time delimited and is due to expire after 2014.

Pediatric Providers and the Future of CHIP

How pediatricians and pediatric subspecialists respond to the incentives provided by CHIP is a critical consideration in evaluating the program's effectiveness over time. Because payments to physicians for patients enrolled in CHIP are generally lower than payments received from commercially

insured patients, the additional insurance coverage that CHIP achieves may result in access and utilization improvements for CHIP patients, which, although laudable, are smaller than they would be were payment rates in this program commensurate with commercial insurance. Indeed, some researchers examining physician response to the program found that, although participation on the part of pediatricians increased with CHIP's introduction, the hours devoted to patient care for all patients decreased,⁴⁴ and the visits to physicians remained unchanged.⁴⁵ These empirical findings indicate that rates of physician payment for CHIP participants will continue to influence how successfully the program achieves its articulated aims. To what extent these developments have implications for the growth of the pediatric workforce in the future is also a matter of considerable importance in the medium- to long-term. Disadvantageous payment rates covering greater proportions of pediatric patients may influence the decisions of those emerging from medical school with significant financial obligations of their own to preferentially consider alternative fields of specialization.

CHIPRA and the ACA have made important contributions to the advancement of health care delivery to near-poor children in recent years and have the potential to accomplish more so in years to come. Going forward, there is a series of issues that the pediatric community must continue to monitor to preserve the advances that have been made and to expand on them where possible. The ACA has mandated that income thresholds for CHIP are to remain constant through 2019 (although the federal government has yet to appropriate funds for the program beyond 2015), but state-by-state variability in cost sharing in the form of premiums, deductibles, and

coinsurance for CHIP stand-alone programs will need to be minimized to maintain true access to health care services, especially to subspecialty care. Pediatricians and families must continue to assess vigilantly the comprehensiveness of benefit packages available under the program, because these features will also vary from state to state. Policy makers will need to set payment rates at adequate levels if a significant proportion of the pediatric community is to engage actively in the care of CHIP enrollees. All those with an interest in advancing child well-being must monitor closely eligibility and benefits for emancipated minors, for children up to 26 years of age, for foster children once they reach the age of majority, for children of undocumented immigrants, and other vulnerable populations. Finally, the relationship between CHIP and the new health care marketplaces must be clearly delineated to ensure that the benefits for children are maintained at least at the present level and that the needs of children are not overlooked as these new structures are being created.

RECOMMENDATIONS

In view of the accomplishments of the CHIP program and the changing dynamics in the health care landscape, the American Academy of Pediatrics (AAP) makes the following recommendations with respect to this program:

1. Fully fund CHIP through 2019.

- Extend the current appropriations formula beyond the 2015 date to continue comprehensive funding of CHIP through 2019.
- Support maintenance of effort for eligibility thresholds and enrollment and renewal procedures for children in CHIP through 2019.
- Maintain the enhanced federal matching rate for CHIP to

encourage states to take advantage of these funds.

- Continue the performance bonuses program beyond fiscal year 2013 to encourage states to innovate with respect to enrollment and retention policies.
 - Maintain contingency funds for states that experience funding shortfalls.
 - Strongly consider transforming CHIP from a block grant program to an entitlement for children in families with incomes less than 300% of the federal poverty level with sliding scale subsidies to eliminate the possibility of denial of coverage because of state caps on spending.
- ### 2. Expand awareness of CHIP among eligible families.
- Encourage state and local departments of health to develop culturally appropriate written and Web-based outreach materials focused on families with incomes that meet CHIP eligibility criteria, concentrating particularly on children with special health care needs.
 - Expand the availability of AAP-generated resources using plain language principles,⁴⁶ and partner with other public and private organizations to produce resources that individual pediatricians can use in their offices to encourage families to enroll in CHIP programs, when applicable.
- ### 3. Facilitate access to CHIP by eligible children.
- Mandate all states to adopt automatic coverage for newborns, and require or incentivize multi-year (5-year) continuous eligibility in Medicaid/CHIP for newborns/infants.
 - Mandate all states to adopt 12-month continuous eligibility

for children and pregnant women in CHIP and Medicaid.

- Mandate all states to automatically enroll all children participating in the Supplemental Nutrition Assistance Program into Medicaid or CHIP.
- Streamline CHIP enrollment and renewal procedures by allowing self-declared income, using passive renewal procedures, eliminating face-to-face renewal encounters, and improving communication with families regarding renewal procedures.
- Coordinate CHIP enrollment efforts with community-based programs that work to enroll uninsured patients in Medicaid, new insurance exchanges, or other appropriate sources of health insurance.
- Expand the use of technology to facilitate enrollment and renewal by the use of prepopulated forms and the expansion of Express Lane eligibility that coordinates enrollment in CHIP with eligibility or enrollment in other public support programs, such as Temporary Assistance for Needy Families (TANF), the Supplemental Nutrition Assistance Program, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), etc.
- Decrease or eliminate enrollment fees and eliminate “lock-out” periods after disenrollment from CHIP for failure to pay premiums.
- Eliminate waiting periods for enrollment into CHIP after loss of employer-based insurance.
- Encourage states to take advantage of the provision in ACA that enables state programs to offer CHIP enrollment to children of

state employees who qualify for the program.

- Maintain eligibility levels and performance bonuses for states that exceed CHIP enrollment targets.
 - Eliminate the discrimination against undocumented children by allowing them access to the CHIP program if they meet other eligibility criteria.
 - Encourage all states to take advantage of the option to cover documented immigrant children through provisions in the Immigrant Children Health Insurance Act provisions of the CHIPRA legislation.
 - Allow youth who are considered “lawfully present” under the Deferred Action for Childhood Arrivals (DACA) program to qualify for Medicaid, CHIP, or tax credits in the marketplace.
 - Strongly consider allowing all children, “under color of law,” regardless of citizenship status to enroll in CHIP.
 - Extend Medicaid/CHIP coverage to age 21, and extend coverage to age 26 for children with special needs.
 - Extend age-appropriate coverage to infants of mothers who are covered under the “age 26” provision.
 - Auto-enroll youth leaving the juvenile justice system into Medicaid or CHIP, and extend coverage for former juvenile justice youth up to age 26 to align with available coverage for children aging out of the foster care system.
4. Work to reconcile stipulations in CHIPRA and the ACA.
- Eliminate “premium stacking” for families in states with separate CHIP programs in which

parents are eligible to enter the newly created marketplaces so that families whose adult members enter the marketplaces are not paying separate uncoordinated premiums for children and adults.

- Require the use of family, rather than individual, premiums for calculating the percentage of income devoted to employer-sponsored health care insurance in determining who is eligible for premium tax credits under provisions of §32B(c)2(C) of the ACA; or alternatively, enable these families to choose CHIP to cover their children.
- Eliminate the 4-week gap in coverage for children transitioning from CHIP to marketplace coverage.
- Work with states to address churning of children between plans by continuing 12-month continuous enrollment and requiring insurers to allow continuation of a child's medical home irrespective of payer (see recommendations on churning in the Medicaid and CHIP Payment and Access Commission's March 2013 Report to Congress, pages 26–43⁴⁷).
- Encourage all states to opt into the Medicaid expansions available through the ACA to cover more parents, thereby increasing the likelihood that their children will acquire health insurance.
- Allow special consideration to be given to families with unique custody circumstances, such as those with parents who are enrolled in marketplaces but whose children are eligible for CHIP, families of foster children, or those with joint custody, nonparental guardianship, or undocumented

parents where knowledge of potential coverage options for children may be limited.

5. Maximize comprehensive coverage and affordability for children in CHIP.
 - Require the adoption of state-level requirements that insurance packages contracted by stand-alone CHIP programs meet essential health benefits packages that also adhere to *Bright Futures* guidelines⁴⁸ with respect to the provision of primary preventive, screening, diagnostic, interventional, subspecialty, dental, surgical, mental health, and palliative care and include all benefits outlined in the AAP policy statement "Scope of Health Care Benefits for Children From Birth Through Age 26."⁴⁹
 - Require/reinforce a defined dental, vision, mental health, and habilitative service benefit for children.
 - Require the National Association of Insurance Commissioners (NAIC) definition of habilitation as a required benefit for all plans.
 - Collect information on compliance with parity in mental health benefits in CHIP plans.
 - Consider the extension of eligibility for the Vaccines for Children Program to all children in non-Medicaid CHIP programs in all states.
 - Maintain the prohibition against any cost sharing for preventive care services, including immunizations, in stand-alone CHIP programs.
 - Prohibit the use of any cost-sharing arrangements in CHIP that shift costs to pediatricians, hospitals, or other health care providers.
- Strengthen and clarify tracking of all out-of-pocket payments across medical and dental benefits in CHIP to ensure that families do not pay beyond 5% of household income.
6. Support the quality measurement provisions incorporated into CHIPRA.
 - Establish incentives to encourage states to report on the full core measure set, and eventually require standardized reporting by states of all quality measures in the pediatric core set.
 - Establish an advisory panel regarding pediatric quality.
 - Sustain and extend support for CHIPRA-funded Centers of Excellence to develop pediatric measures.
 - Analyze effectiveness of the pediatric electronic health record format and work to support the development of a unified pediatric electronic health record that could be widely adapted in multiple practice settings.
 - Encourage the development, dissemination, monitoring, and reporting on a set of child-specific quality measures beyond the initial core set of 24 metrics that will enable policy makers, practitioners, patients, and families to compare outcomes across practice settings, regions, and insurance plans.
 - Allow CHIP case-mix calculations for HITECH Act electronic health records incentive payments.⁵⁰
 - Support ongoing funding at the National Institutes of Health and other federal agencies for the development, dissemination, implementation, and evaluation of these pediatric-specific quality measures.
- Encourage specifically, direct comparisons wherever possible in quality measures, outcome evaluations, and cost-effectiveness between CHIP enrollees and children who end up enrolled in market-place insurance plans.
- Build on existing state demonstration grants to continue and expand a focus on quality outcomes at the state level.
- Work to sustain the Medicaid and CHIP Payment and Access Commission (MACPAC) to advance policy analysis and health services research as they apply to CHIP.
7. Ensure adequate payment for practitioners who care for CHIP patients.
 - Require plans that contract with stand-alone CHIP programs to cover full costs of all new vaccines effective on the publication date of recommendations by the AAP or the Centers for Disease Control and Prevention in the *Morbidity and Mortality Weekly Report (MMWR)*. Coverage and payments must cover the costs of the vaccine adequately such that they include the total direct and indirect vaccine expense overhead as well as the related immunization administration service. Payment for the vaccine product should be at least 125% of the current Centers for Disease Control and Prevention vaccine price list. Payment for immunization administration must be at least 100% of the current Medicare Resource-Based Relative Value Scale (RBRVS) physician fee schedule.
 - To improve the adoption of effective medical home strategies by primary care pediatricians, require CHIP payers for

stand-alone programs to include payments for care coordination, telephone consultation, case management, hospital transition planning, and subspecialty care coordination.

- Create and maintain funding mechanisms to award achievement of recognized, evidence-based, outcome-driven quality-of-care standards for CHIP enrollees.
- Extend Medicaid payment parity permanently and extend parity to all billable services, including specialists and subspecialists.

CONCLUSIONS

Near-poor children in the United States have derived enormous benefits from

CHIP since its inception 16 years ago. The reauthorization of this landmark social insurance program in 2009 strengthened many of its most important elements and added innovative features that broadened its reach. With the passage of the ACA, the approach that the United States will adopt for this vulnerable segment of the pediatric population after 2015 is now subject to some uncertainty. Whether CHIP proves to have been an interim approach that is ultimately replaced by universal coverage through a combination of Medicaid, employer-sponsored health insurance, and insurance exchanges or by adoption of a single-payer system or whether CHIP endures in its current form even after full implementation of the ACA, it is vital for the health of near-

poor children that the principles of expanded access, affordable coverage, generous benefits, and quality monitoring be essential elements in the provision of health care services now and into the future.

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Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays

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- *Clinical Report*

CLINICAL REPORT

Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays

John B. Moeschler, MD, MS, FAAP, FACMG, Michael Shevell, MDCM, FRCP, and COMMITTEE ON GENETICS

ABBREVIATIONS

AAP—American Academy of Pediatrics
CMA—chromosome microarray
CNS—central nervous system
CNV—copy number variant
CT—computed tomography
FISH—fluorescent in situ hybridization
GAA—guanidinoacetate
GDD—global developmental delay
ID—intellectual disability
XLID—X-linked intellectual disability

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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Global developmental delay and intellectual disability are relatively common pediatric conditions. This report describes the recommended clinical genetics diagnostic approach. The report is based on a review of published reports, most consisting of medium to large case series of diagnostic tests used, and the proportion of those that led to a diagnosis in such patients. Chromosome microarray is designated as a first-line test and replaces the standard karyotype and fluorescent in situ hybridization subtelomere tests for the child with intellectual disability of unknown etiology. Fragile X testing remains an important first-line test. The importance of considering testing for inborn errors of metabolism in this population is supported by a recent systematic review of the literature and several case series recently published. The role of brain MRI remains important in certain patients. There is also a discussion of the emerging literature on the use of whole-exome sequencing as a diagnostic test in this population. Finally, the importance of intentional comanagement among families, the medical home, and the clinical genetics specialty clinic is discussed. *Pediatrics* 2014;134:e903–e918

The purpose of this clinical report of the American Academy of Pediatrics (AAP) is to describe an optimal medical genetics evaluation of the child with intellectual disability (ID) or global developmental delays (GDDs). The intention is to assist the medical home in preparing families properly for the medical genetics evaluation process. This report addresses the advances in diagnosis and treatment of children with intellectual disabilities since the publication of the original AAP clinical report in 2006¹ and provides current guidance for the medical genetics evaluation. One intention is to inform primary care providers in the setting of the medical home so that they and families are knowledgeable about the purpose and process of the genetics evaluation. This report will emphasize advances in genetic diagnosis while updating information regarding the appropriate evaluation for inborn errors of metabolism and the role of imaging in this context. The reader is referred to the 2006 clinical report for background information that remains relevant, including the roles of the medical home or pediatric primary care provider.

This clinical report will not address the importance of developmental screening in the medical home, nor will it address the diagnostic

evaluation of the child with an autism spectrum disorder who happens to have ID as a co-occurring disability. (For AAP guidance related to Autism Spectrum Disorders, see Johnson and Myers.²)

For both pediatric primary care providers and families, there are specific benefits to establishing an etiologic diagnosis (Table 1): clarification of etiology; provision of prognosis or expected clinical course; discussion of genetic mechanism(s) and recurrence risks; refined treatment options; the avoidance of unnecessary and redundant diagnostic tests; information regarding treatment, symptom management, or surveillance for known complications; provision of condition-specific family support; access to research treatment protocols; and the opportunity for comanagement of patients, as appropriate, in the context of a medical home to ensure the best health, social, and health care services satisfaction outcomes for the child and family. The presence of an accurate etiologic diagnosis along with a knowledgeable, experienced, expert clinician is one factor in improving the psychosocial outcomes for children and with

intellectual disabilities and their families.^{3–5} Although perhaps difficult to measure, this “healing touch” contributes to the general well-being of the family. “As physicians we have experience with other children who have the same disorder, access to management programs, knowledge of the prognosis, awareness of research on understanding the disease and many other elements that when shared with the parents will give them a feeling that some control is possible.”⁵

Makela et al⁶ studied, in depth, 20 families of children with ID with and without an etiologic diagnosis and found that these families had specific stated needs and feelings about what a genetic diagnosis offers:

1. Validation: a diagnosis established that the problem (ID) was credible, which empowered them to advocate for their child.
2. Information: a diagnosis was felt to help guide expectations and management immediately and provide hope for treatment or cure in future.
3. Procuring services: the diagnosis assisted families in obtaining desired services, particularly in schools.
4. Support: families expressed the need for emotional companionship that a specific diagnosis (or “similar challenges”) assisted in accessing.
5. Need to know: families widely differed in their “need to know” a specific diagnosis, ranging from strong to indifferent.
6. Prenatal testing: families varied in their emotions, thoughts, and actions regarding prenatal genetic diagnosis.

For some families in the Makela et al⁶ study, the clinical diagnosis of autism, for example, was sufficient and often more useful than “a rare but specific etiological diagnosis.” These authors report that “all of the families would

have preferred to have an [etiologic] diagnosis, if given the option,” particularly early in the course of the symptoms.

As was true of the 2006 clinical report, this clinical report will not address the etiologic evaluation of young children who are diagnosed with cerebral palsy, autism, or a single-domain developmental delay (gross motor delay or specific language impairment).¹ Some children will present both with GDD and clinical features of autism. In such cases, the judgment of the clinical geneticist will be important in determining the evaluation of the child depending on the primary neurodevelopmental diagnosis. It is recognized that the determination that an infant or young child has a cognitive disability can be a matter of clinical judgment, and it is important for the pediatrician and consulting clinical geneticist to discuss this before deciding on the best approach to the diagnostic evaluation.”¹

INTELLECTUAL DISABILITY

ID is a developmental disability presenting in infancy or the early childhood years, although in some cases, it cannot be diagnosed until the child is older than ~5 years of age, when standardized measures of developmental skills become more reliable and valid. The American Association on Intellectual and Developmental Disability defines ID by using measures of 3 domains: intelligence (IQ), adaptive behavior, and systems of supports afforded the individual.⁷ Thus, one cannot rely solely on the measure of IQ to define ID. More recently, the term ID has been suggested to replace “mental retardation.”^{7,8} For the purposes of this clinical report, the American Association on Intellectual and Developmental Disability definition is used: “Intellectual disability is a disability characterized by

TABLE 1 The Purposes of the Comprehensive Medical Genetics Evaluation of the Young Child With GDD or ID

1. Clarification of etiology
2. Provision of prognosis or expected clinical course
3. Discussion of genetic mechanism(s) and recurrence risks
4. Refined treatment options
5. Avoidance of unnecessary or redundant diagnostic tests
6. Information regarding treatment, symptom management, or surveillance for known complications
7. Provision of condition-specific family support
8. Access to research treatment protocols
9. Opportunity for comanagement of appropriate patients in the context of a medical home to ensure the best health, social, and health care services satisfaction outcomes for the child and family

significant limitations both in intellectual functioning and in adaptive behavior as expressed in conceptual, social and practical adaptive skills. The disability originates before age 18 years.”⁷ The prevalence of ID is estimated to be between 1% and 3%. Lifetime costs (direct and indirect) to support individuals with ID are large, estimated to be an average of approximately \$1 million per person.⁹

Global Developmental Delay

Identifying the type of developmental delay is an important preliminary step, because typing influences the path of investigation later undertaken. GDD is defined as a significant delay in 2 or more developmental domains, including gross or fine motor, speech/language, cognitive, social/personal, and activities of daily living and is thought to predict a future diagnosis of ID.¹⁰ Such delays require accurate documentation by using norm-referenced and age-appropriate standardized measures of development administered by experienced developmental specialists. The term GDD is reserved for younger children (ie, typically younger than 5 years), whereas the term ID is usually applied to older children for whom IQ testing is valid and reliable. Children with GDD are those who present with delays in the attainment of developmental milestones at the expected age; this implies deficits in learning and adaptation, which suggests that the delays are significant and predict later ID. However, delays in development, especially those that are mild, may be transient and lack predictive reliability for ID or other developmental disabilities. For the purposes of this report, children with delays in a single developmental domain (for example, isolated mild speech delay) should not be considered appropriate candidates for the comprehensive genetic evaluation process set forth here. The prevalence

of GDD is estimated to be 1% to 3%, similar to that of ID.

Diagnosis

Schaefer and Bodensteiner¹¹ wrote that a specific diagnosis is that which “can be translated into useful clinical information for the family, including providing information about prognosis, recurrence risks, and preferred modes of available therapy.” For example, agenesis of the corpus callosum is considered a sign and not a diagnosis, whereas the autosomal-recessive Acrocallosal syndrome (agenesis of the corpus callosum and polydactyly) is a clinical diagnosis. Van Karnebeek et al¹² defined etiologic diagnosis as “sufficient literature evidence...to make a causal relationship of the disorder with mental retardation likely, and if it met the Schaefer-Bodensteiner definition.” This clinical report will use this Van Karnebeek modification of the Schaefer–Bodensteiner definition and, thus, includes the etiology (genetic mutation or genomic abnormality) as an essential element to the definition of a diagnosis.

Recommendations are best when established from considerable empirical evidence on the quality, yield, and usefulness of the various diagnostic investigations appropriate to the clinical situation. The evidence for this clinical report is largely based on many small- or medium-size case series and on expert opinion. The report is based on a review of the literature by the authors.

Highlights in This Clinical Report

Significant changes in genetic diagnosis in the last several years have made the 2006 clinical report out-of-date. First, the chromosome microarray (CMA) is now considered a first-line clinical diagnostic test for children who present with GDD/ID of unknown cause. Second, this report

highlights a renewed emphasis on the identification of “treatable” causes of GDD/ID with the recommendation to consider screening for inborn errors of metabolism in all patients with unknown etiology for GDD/ID.¹³

Nevertheless, the approach to the patient remains familiar to pediatric primary care providers and includes the child’s medical history (including prenatal and birth histories); the family history, which includes construction and analysis of a pedigree of 3 generations or more; the physical and neurologic examinations emphasizing the examination for minor anomalies (the “dysmorphology examination”); and the examination for neurologic or behavioral signs that might suggest a specific recognizable syndrome or diagnosis. After the clinical genetic evaluation, judicious use of laboratory tests, imaging, and other consultations on the basis of best evidence are important in establishing the diagnosis and for care planning.

CHROMOSOME MICROARRAY

CMA now should be considered a first-tier diagnostic test in all children with GDD/ID for whom the causal diagnosis is not known. G-banded karyotyping historically has been the standard first-tier test for detection of genetic imbalance in patients with GDD/ID for more than 35 years. CMA is now the standard for diagnosis of patients with GDD/ID, as well as other conditions, such as autism spectrum disorders or multiple congenital anomalies.^{14–24} The G-banded karyotype allows a cytogeneticist to visualize and analyze chromosomes for chromosomal rearrangements, including chromosomal gains (duplications) and losses (deletions). CMA performs a similar function, but at a much “higher resolution,” for genomic imbalances, thus increasing the sensitivity substantially. In their recent review of the CMA literature,

Visser et al²⁵ report the diagnostic rate of CMA to be at least twice that of the standard karyotype. CMA, as used in this clinical report, encompasses all current types of array-based genomic copy number analyses, including array-based comparative genomic hybridization and single-nucleotide polymorphism arrays (see Miller et al¹⁵ for a review of array types). With these techniques, a patient's genome is examined for detection of gains or losses of genome material, including those too small to be detectable by standard G-banded chromosome studies.^{26,27} CMA replaces the standard karyotype ("chromosomes") and fluorescent in situ hybridization (FISH) testing for patients presenting with GDD/ID of unknown cause. The standard karyotype and certain FISH tests remain important to diagnostic testing but now only in limited clinical situations (see Manning and Hudgins¹⁴) in which a specific condition is suspected (eg, Down syndrome or Williams syndrome). The discussion of CMA does not include whole-genome sequencing, exome sequencing, or "next-generation" genome sequencing; these are discussed in the "emerging technologies" section of this report.

Twenty-eight case series have been published addressing the rate of diagnosis by CMA of patients presenting with GDD/ID.²⁸ The studies vary by subject criteria and type of microarray technique and reflect rapid changes in technology over recent years. Nevertheless, the diagnostic yield for all current CMA is estimated at 12% for patients with GDD/ID.^{14–29} CMA is the single most efficient diagnostic test, after the history and examination by a specialist in GDD/ID.

CMA techniques or "platforms" vary. Generally, CMA compares DNA content from 2 differentially labeled genomes: the patient and a control. In the early techniques, 2 genomes were cohybridized, typically onto a glass microscope

slide on which cloned or synthesized control DNA fragments had been immobilized. Arrays have been built with a variety of DNA substrates that may include oligonucleotides, complementary DNAs, or bacterial artificial chromosomes. The arrays might be whole-genome arrays, which are designed to cover the entire genome, or targeted arrays, which target known pathologic loci, the telomeres, and pericentromeric regions. Some laboratories offer chromosome-specific arrays (eg, for nonsyndromic X-linked ID [XLID]).³⁰ The primary advantage of CMA over the standard karyotype or later FISH techniques is the ability of CMA to detect DNA copy changes simultaneously at multiple loci in a genome in one "experiment" or test. The copy number change (or copy number variant [CNV]) may include deletions, duplications, or amplifications at any locus, as long as that region is represented on the array. CMA, independent of whether it is "whole genome" or "targeted" and what type of DNA substrate (single-nucleotide polymorphisms,³¹ oligonucleotides, complementary DNAs, or bacterial artificial chromosomes),³² identifies deletions and/or duplications of chromosome material with a high degree of sensitivity in a more efficient manner than FISH techniques. Two main factors define the resolution of CMA: (1) the size of the nucleic acid targets; and (2) the density of coverage over the genome. The smaller the size of the nucleic acid targets and the more contiguous the targets on the native chromosome are, the higher the resolution is. As with the standard karyotype, one result of the CMA test can be "of uncertain significance," (ie, expert interpretation is required, because some deletions or duplications may not be clearly pathogenic or benign). Miller et al¹⁵ describe an effort to develop an international consortium of laboratories to address questions surrounding array-based testing interpretation. This

International Standard Cytogenomic Array Consortium¹⁵ (www.iscaconsortium.org) is investigating the feasibility of establishing a standardized, universal system of reporting and cataloging CMA results, both pathologic and benign, to provide the physician with the most accurate and up-to-date information.

It is important for the primary care pediatrician to work closely with the clinical geneticist and the diagnostic laboratory when interpreting CMA test results, particularly when "variants of unknown significance" are identified. In general, CNVs are assigned the following interpretations: (1) pathogenic (ie, abnormal, well-established syndromes, *de novo* variants, and large changes); (2) variants of unknown significance; and (3) likely benign.¹⁵ These interpretations are not essentially different than those seen in the standard G-banded karyotype. It is important to note that not all commercial health plans in the United States include this testing as a covered benefit when ordered by the primary care pediatrician; others do not cover it even when ordered by the medical geneticist. Typically, the medical genetics team has knowledge and experience in matters of payment for testing.

The literature does not stratify the diagnostic rates of CMA by severity of disability. In addition, there is substantial literature supporting the multiple factors (eg, social, environmental, economic, genetic) that contribute to mild disability.³³ Consequently, it remains within the judgment of the medical geneticist as to whether it is warranted to test the patient with mild (and familial) ID for pathogenic CNVs. In their review, Visser et al²⁵ reported on several recurrent deletion or duplication syndromes with mild disability and commented on the variable penetrance of the more common CNV conditions, such as 1q21.1

microdeletion, 1q21.1 microduplication, 3q29 microduplication, and 12q14 microdeletion. Some of these are also inherited. Consequently, among families with more than one member with disability, it remains challenging for the medical geneticist to know for which patient with GDD/ID CMA testing is not warranted.

Recent efforts to evaluate reporting of CNVs among clinical laboratories indicate variability of interpretation because of platform variability in sensitivity.^{34,35} Thus, the interpretation of CMA test abnormal results and variants of unknown significance, and the subsequent counseling of families should be performed in all cases by a medical geneticist and certified genetic counselor in collaboration with the reference laboratory and platform used. Test variability is resolving as a result of international collaborations.³⁶ With large data sets, the functional impact (or lack thereof) of very rare CNVs is better understood. Still, there will continue to be rare or unique CNVs for which interpretation remain ambiguous. The medical geneticist is best equipped to interpret such information to families and the medical home.

SCREENING FOR INBORN ERRORS OF METABOLISM

Since the 2006 AAP clinical report, several additional reports have been published regarding metabolic testing for a cause of ID.^{13,37–40} The percentage of patients with identifiable metabolic disorders as cause of the ID ranges from 1% to 5% in these reports, a range similar to those studies included in the 2006 clinical report. Likewise, these newer published case series varied by site, age range of patients, time frame, study protocol, and results. However, they do bring renewed focus to treatable metabolic disorders.¹³ Furthermore, some of the disorders identified

are not included currently in any newborn screening blood spot panels. Although the prevalence of inherited metabolic conditions is relatively low (0% to 5% in these studies), the potential for improved outcomes after diagnosis and treatment is high.⁴¹

In 2005, Van Karnebeek et al⁴⁰ reported on a comprehensive genetic diagnostic evaluation of 281 consecutive patients referred to an academic center in the Netherlands. All patients were subjected to a protocol for evaluation and studies were performed for all patients with an initially unrecognized cause of mental retardation and included urinary screen for amino acids, organic acids, oligosaccharides, acid mucopolysaccharides, and uric acid; plasma concentrations of total cholesterol and diene sterols of 7- and 8-dehydrocholesterol to identify defects in the distal cholesterol pathway; and a serum test to screen for congenital disorders of glycosylation (test names such as “carbohydrate-deficient transferrin”). In individual patients, other searches were performed as deemed necessary depending on results of earlier studies. This approach identified 7 (4.6%) subjects with “certain or probable” metabolic disorders among those who completed the metabolic screening ($n = 216$). None of the 176 screening tests for plasma amino acids and urine organic acids was abnormal. Four children (1.4%) with congenital disorders of glycosylation were identified by serum sialotransferrins, 2 children had abnormal serum cholesterol and 7-dehydrocholesterol concentrations suggestive of Smith-Lemli-Opitz syndrome, 2 had evidence of a mitochondrial disorder, 1 had evidence of a peroxisomal disorder, and 1 had abnormal cerebrospinal fluid biogenic amine concentrations. These authors concluded that “screening for glycosylation defects proved useful,

whereas the yield of organic acid and amino acid screening was negligible.”

In a similar study from the Netherlands done more recently, Engbers et al³⁹ reported on metabolic testing that was performed in 433 children whose GDD/ID remained unexplained after genetic/metabolic testing, which included a standard karyotype; urine screen for amino acids, organic acids, mucopolysaccharides, oligosaccharides, uric acid, sialic acid, purines, and pyrimidines; and plasma for amino acids, acylcarnitines, and sialotransferrins. Screenings were repeated, and additional testing, including cerebrospinal fluid studies, was guided by clinical suspicion. Metabolic disorders were identified and confirmed in 12 of these patients (2.7%), including 3 with mitochondrial disorders; 2 with creatine transporter disorders; 2 with short-chain acyl-coenzyme A dehydrogenase deficiency; and 1 each with Sanfilippo IIIa, a peroxisomal disorder; a congenital disorder of glycosylation; 5-methyltetrahydrofolate reductase deficiency; and deficiency of the GLUT1 glucose transporter.

Other studies have focused on the prevalence of disorders of creatine synthesis and transport. Lion-François et al³⁷ reported on 188 children referred over a period of 18 months with “unexplained mild to severe mental retardation, normal karyotype, and absence of fragile X syndrome” who were prospectively screened for congenital creatine deficiency syndromes. Children were from diverse ethnic backgrounds. Children with “polymalformative syndromes” were excluded. There were 114 boys (61%) and 74 girls (39%) studied. Creatine metabolism was evaluated by using creatine/creatinine and guanidinoacetate (GAA)-to-creatinine ratios on a spot urine screen. Diagnosis was further confirmed by using brain proton magnetic resonance spectroscopy and mutation screening by DNA sequence analysis in

either the *SLC6A8* (creatine transporter defect) or the *GAMT* genes. This resulted in a diagnosis in 5 boys (2.7% of all; 4.4% of boys). No affected girls were identified among the 74 studied. All 5 boys also were late to walk, and 3 had “autistic features.” The authors concluded that all patients with undiagnosed ID have urine screened for creatine-to-creatinine ratio and GAA-to-creatine ratio. Similarly, Caldeira Araujo et al³⁸ studied 180 adults with ID institutionalized in Portugal, screening them for congenital creatine deficiency syndromes. Their protocol involved screening all subjects for urine and plasma uric acid and creatinine. Patients with an increased urinary uric acid-to-creatinine ratio and/or decreased creatinine were subjected to the analysis of GAA. *GAMT* activity was measured in lymphocytes and followed by *GAMT* gene analysis. This resulted in identifying 5 individuals (2.8%) from 2 families with *GAMT* deficiency. A larger but less selective study of 1600 unrelated male and female children with GDD/ID and/or autism found that 34 (2.1%) had abnormal urine creatine-to-creatinine ratios, although only 10 (0.6%) had abnormal repeat tests and only 3 (0.2%) were found to have an *SLC6A8* mutation.⁴² Clark et al⁴³ identified *SLC6A8* mutations in 0.5% of 478 unrelated boys with unexplained GDD/ID.

Recently, van Karnebeek and Stockler reported^{13,42} on a systematic literature review of metabolic disorders “presenting with intellectual disability as a major feature.” The authors identified 81 treatable genetic metabolic disorders presenting with ID as a major feature. Of these disorders, 50 conditions (62%) were identified by routinely available tests (Tables 2 and 3). Therapeutic modalities with proven effect included diet, cofactor/vitamin supplements, substrate inhibition, en-

zyme replacement, and hematopoietic stem cell transplant. The effect on outcome (IQ, developmental performance, behavior, epilepsy, and neuroimaging) varied from improvement to halting or slowing neurocognitive regression. The authors emphasized the approach as one that potentially has significant impact on patient outcomes: “This approach revisits current paradigms for the diagnostic evaluation of ID. It implies treatability as the premise in the etiologic work-up and applies evidence-based medicine to rare diseases.” Van Karnebeek and Stockler^{13,42} reported on 130 patients with ID who were “tested” per this metabolic protocol; of these, 6 (4.6%) had confirmed treatable inborn errors of metabolism and another 5 (3.8%) had “probable” treatable inborn error of metabolism.

This literature supports the need to consider screening children presenting with GDD/ID for treatable metabolic conditions. Many metabolic screening tests are readily available to the medical home and/or local hospital laboratory service. Furthermore, the costs for these metabolic screening tests are relatively low.

GENETIC TESTING FOR MENDELIAN DISORDERS

For patients in whom a diagnosis is suspected, diagnostic molecular genetic testing is required to confirm the diagnosis so that proper health care is

implemented and so that reliable genetic counseling can be provided. For patients with a clinical diagnosis of a Mendelian disorder that is certain, molecular genetic diagnostic testing usually is not required to establish the diagnosis but may be useful for health care planning. However, for carrier testing or for genetic counseling of family members, it is often essential to know the specific gene mutation in the proband.

For patients with GDD/ID for whom the diagnosis is not known, molecular genetic diagnostic testing is necessary, under certain circumstances, which is discussed in the next section.

MALE GENDER

There is an approximate 40% excess of boys in all studies of prevalence and incidence of ID.^{44,45} Part of this distortion of the gender ratio is attributable to X-linked genetic disorders.⁴⁶ Consequently, genetic testing for X-linked genes in boys with GDD/ID is often warranted, particularly in patients whose pedigree is suggestive of an X-linked condition. In addition, for several reasons, research in X-linked genes that cause ID is advanced over autosomal genes,^{46,47} thus accelerating the clinical capacity to diagnose XLID over autosomal forms.

Most common of these is fragile X syndrome, although the prevalence of all other X-linked genes involved in ID

TABLE 2 Metabolic Screening Tests

Specimen ^a	Test	Notes
Blood	Amino acids Homocysteine Acylcarnitine profile	See Table 3
Urine	Organic acids GAA/creatine metabolites Purines and pyrimidines Mucopolysaccharide screen Oligosaccharide screen	

See Fig 1.

^a Serum lead, thyroid function studies not included as “metabolic tests” and to be ordered per clinician judgment.

TABLE 3 Metabolic Conditions Identified by Tests Listed

PAAs	P-HCY	Acylcarn	UOA	UPP	UGAA/Cr	UMPS	UOligo
Argininosuccinic aciduria ^a	Cobalamin C deficiency	Cobalamin C deficiency	β-ketothiolase deficiency	Pyrimidine 5'nucleotidase superactivity	AGAT deficiency	Hurler	α-mannosidosis
Citrullinemia ^a	Cobalamin D deficiency	Cobalamin D deficiency	Cobalamin A deficiency	Molybdenum cofactor type A deficiency	GAMT deficiency	Hunter	Aspartylglucosaminuria
Citrullinemia, type II ^a	Cobalamin F deficiency	Cobalamin F deficiency	Cobalamin B deficiency		Creatine transporter defect	Sanfilippo A, B, C	
CPS deficiency ^a	Cobalamin E deficiency	Ethylmalonic encephalopathy	Cobalamin C deficiency			Sly (MPS VI)	
Argininemia ^a	Cobalamin G deficiency	Isovaleric acidemia ^a	Cobalamin D deficiency				
HHH syndrome	MTHFR deficiency ^a	3-methylcrotonyl glycinuria	Cobalamin F deficiency				
Maple syrup urine disease, variant	Homocystinuria	PPA ^a	Ethylmalonic encephalopathy				
NAGS deficiency ^a		Tyrosinemia, type II	GA, type I				
MTHFR deficiency ^a			GA, type II				
OTC deficiency ^a			HMG-CoA Lyase deficiency				
PKU			Holocarboxylase synthetase deficiency				
PDH complex deficiency			Homocystinuria				
Tyrosinemia, type II			Isovaleric acidemia ^a				
			3-methylcrotonyl glycinuria				
			3-methylglutaconic aciduria				
			MMA ^a				
			MHBD deficiency				
			PPA ^a				
			SCOT deficiency				
			SSADH deficiency				
			Tyrosinemia, type II				

Adapted from van Karnebeek and Stockler.⁴¹

Acylcarn, acylcarnitine profile; CPS, carbamyl phosphate synthetase; GA, glutaric acidemia; HHH, hyperornithinemia-hyperammonemia-homocitrullinuria; HMG-CoA, 3-hydroxy-3-methylglutaryl-coenzyme A; MHBD, 2-methyl-3-hydroxybutyryl CoA dehydrogenase; MMA, methylmalonic acidemia; MTHFR, methylenetetrahydrofolate reductase; NAGS, N-acetylglutamate synthase; OTC, ornithine transcarbamylase; PAA, plasma amino acids; PDH, pyruvate dehydrogenase; P-HCY, plasma homocysteine; PKU, phenylketonuria; PPA, propionic acid; SCOT, succinyl-CoA:3-ketoacid CoA transferase; SSADH, succinic semialdehyde dehydrogenase; UGAA/creat, urine guanidino acid/creatinine metabolites; UMPS, urine mucopolysaccharides qualitative screen (glycosaminoglycans); UOA, urine organic acids; UOGS, urine oligosaccharides; UPP, urine purines and pyrimidines.

^a Late-onset form of condition listed; some conditions are identified by more than 1 metabolic test.

far exceeds that of fragile X syndrome alone.⁴⁶ Fragile X testing should be performed in all boys and girls with GDD/ID of unknown cause. Of boys with GDD/ID of uncertain cause, 2% to 3% will have fragile X syndrome (full mutation of *FMR1*, >200 CGG repeats), as will 1% to 2% of girls (full mutation).⁴⁸

GENETIC TESTING FOR NONSPECIFIC XLID

Stevenson and Schwartz⁴⁹ suggest 2 clinical categories for those with XLID: syndromal and nonsyndromal. Syndromal refers to patients in whom physical or neurologic signs suggest a specific diagnosis; nonsyndromal refers to those with no signs or symptoms to guide the diagnostic process. Using this classification has practical applicability, because the pediatric primary care provider can establish a specific XLID syndrome on the basis of clinical findings. In contrast, nonsyndromal conditions can only be distinguished on the basis of the knowledge of their causative gene.⁵⁰ In excess of 215 XLID conditions have been recorded, and >90 XLID genes have been identified.^{46,50}

To address male patients with GDD/ID and X-linked inheritance, there are molecular genetic diagnostic “panels” of X-linked genes available clinically. These panels examine many genes in 1 “test sample.” The problem for the clinical evaluation is in which patient to use which test panel, because there is no literature on head-to-head performance of test panels, and the test panels differ somewhat by genes included, test methods used, and the rate of a true pathogenic genetic diagnosis. Nevertheless, the imperative for the diagnostic evaluation remains the same for families and physicians, and there is a place for such testing in the clinical evaluation of children with GDD/ID. For patients with an

X-linked pedigree, genetic testing using one of the panels is clinically indicated. The clinical geneticist is best suited to guide this genetic testing of patients with possible XLID. For patients with “syndromal” XLID (eg, Coffin-Lowry syndrome), a single gene test rather than a gene panel is indicated. Whereas those patients with “nonsyndromal” presentation might best be assessed by using a multigene panel comprising many of the more common nonsyndromal XLID genes. The expected rate of the diagnosis may be high. Stevenson and Schwartz⁴⁶ reported, for example, on 113 cases of nonspecific ID testing using a 9-gene panel of whom 9 (14.2%) had pathogenic mutations identified. de Brouwer et al⁵¹ reported on 600 families with multiple boys with GDD/ID and normal karyotype and *FMR1* testing. Among those families with “an obligate female carrier” (defined by pedigree analysis and linkage studies), a specific gene mutation was identified in 42%. In addition, in those families with more than 2 boys with ID and no obligate female carrier or without linkage to the X chromosome, 17% of the ID cases could be explained by X-linked gene mutations. This very large study suggested that testing of individual boys for X-linked gene mutations is warranted.

Recently, clinical laboratories have begun offering “high-density” X-CMAs to assess for pathogenic CNVs (see previous discussion regarding microarrays) specifically for patients with XLID. Wibley et al⁵⁰ (2010) reported on CNVs in 251 families with evidence of XLID who were investigated by array comparative genomic hybridization on a high-density oligonucleotide X-chromosome array platform. They identified pathogenic CNVs in 10% of families. The high-density arrays for XLID are appropriate in those patients with syndromal or nonsyndromal XLID.

The expected diagnostic rate remains uncertain, although many pathogenic segmental duplications are reported (for a catalog of X-linked mutations and CNVs, see <http://www.ggc.org/research/molecular-studies/xlid.html>).

Whole exome sequencing and whole-genome sequencing are emerging testing technologies for patients with nonspecific XLID. Recently, Tarpey et al⁵² have reported the results of the large-scale systematic resequencing of the coding X chromosome to identify novel genes underlying XLID. Gene coding sequences of 718 X-chromosome genes were screened via Sanger sequencing technology in probands from 208 families with probable XLID. This resequencing screen contributed to the identification of 9 novel XLID-associated genes but identified pathogenic sequence variants in only 35 of 208 (17%) of the cohort families. This figure likely underestimates the general contribution of sequence variants to XLID given the subjects were selected from a pool that had had previous clinical and molecular genetic screening.³⁰

BOYS WITH SUSPECTED OR KNOWN XLID

Table 4 lists some common XLID conditions. In cases in which the diagnosis is not certain, molecular genetic testing of patients for the specific gene is indicated, even if the pedigree does not indicate other affected boys (ie, cannot confirm X-linked inheritance).⁴⁶

FEMALE GENDER AND MECP2 TESTING

Rett syndrome is an X-linked condition that affects girls and results from *MECP2* gene mutations primarily (at least 1 other gene has been determined causal in some patients with typical and atypical Rett syndrome: *CDKL5*). Girls with mutations in the

MECP2 gene do not always present clinically with classic Rett syndrome. Several large case series have examined the rate of pathogenic *MECP2* mutations in girls and boys with ID. The proportion of *MECP2* mutations in these series ranged from 0% to 4.4% with the average of 1.5% among girls with moderate to severe ID.^{53–62} *MECP2* mutations in boys present with severe neonatal encephalopathy and not with GDD/ID.

ADVANCES IN DIAGNOSTIC IMAGING

Currently, the literature does not indicate consensus on the role that neuroimaging, either by computed tomography (CT) or MRI, can play in the evaluation of children with GDD/ID. Current recommendations range from performing brain imaging on all patients with GDD/ID,⁶³ to performing it only on those with indications on clinical examination,¹² to being considered as a second-line investigation to be undertaken when features in addition to GDD are detected either on history or physical examination. The finding of a brain abnormality or anomaly on neuroimaging may lead to the recognition of a specific cause of an individual child's developmental delay/ID in the same way that a dysmorphologic examination might lead to the inference of a particular clinical diagnosis. However, like other major or minor anomalies noted on physical examination, abnormalities on neuroimaging typically are not sufficient for determining the cause of the developmental delay/ID; the underlying precise, and presumably frequently genetic in origin, cause of the brain anomaly is often left unknown. Thus, although a central nervous system (CNS) anomaly (often also called a "CNS dysgenesis") is a useful finding and indeed may be considered, according to the definition of Schaefer and Bodensteiner,¹¹ a useful "diagnosis."

However, it is frequently not an etiologic or syndromic diagnosis. This distinction is not always made in the literature on the utility of neuroimaging in the evaluation of children with developmental delay/ID. The lack of a consistent use of this distinction has led to confusion regarding this particular issue.

Early studies on the use of CT in the evaluation of children with idiopathic ID⁶⁴ indicated a low diagnostic yield for the nonspecific finding of "cerebral atrophy," which did not contribute to clarifying the precise cause of the ID.⁶⁵ Later studies that used MRI to detect CNS abnormalities suggested that MRI was more sensitive than CT, with an increased diagnostic yield.^{10,66} The rate of abnormalities actually detected on imaging varies widely in the literature as a result of many factors, such as subject selection and the method of imaging used (ie, CT or MRI). Schaefer and Bodensteiner,⁶³ in their literature review, found reported ranges of abnormalities from 9% to 80% of those patients studied. Shevell et al¹⁰ reported a similar range of finding in their review. For example, in 3 studies totaling 329 children with developmental delay in which CT was used in almost all patients and MRI was used in but a small sample, a specific cause was determined in 31.4%,⁶⁷ 27%,⁶⁸ and 30%⁶⁹ of the children. In their systematic review of the literature, van Karnebeek et al¹² reported on 9 studies that used MRI in children with ID. The mean rate of abnormalities found was 30%, with a range of 6.2% to 48.7%. These investigators noted that more abnormalities were found in children with moderate to profound ID versus those with borderline to mild ID (mean yield of 30% and 21.2%, respectively). These authors also noted that none of the studies reported on the value of the absence of any neurologic abnormality for a diagnostic workup and

concluded that "the value for finding abnormalities or the absence of abnormalities must be higher" than the 30% mean rate implied.

If neuroimaging is performed in only selected cases, such as children with an abnormal head circumference or an abnormal focal neurologic finding, the rate of abnormalities detected is increased further than when used on a screening basis in children with a normal neurologic examination except for the documentation of developmental delay. Shevell et al⁶⁸ reported that the percentage of abnormalities were 13.9% if neuroimaging was performed on a "screening basis" but increased to 41.2% if performed on "an indicated basis." Griffiths et al⁷⁰ highlighted that the overall risk of having a specific structural abnormality found on MRI scanning was 28% if neurologic symptoms and signs other than developmental delay were present, but if the developmental delay was isolated, the yield was reduced to 7.5%. In a series of 109 children, Verbruggen et al⁷¹ reported an etiologic yield on MRI of 9%. They noted that all of these children had neurologic signs or an abnormal head circumference. In their practice parameter, the American Academy of Neurology and the Child Neurology Society¹⁰ discussed other studies on smaller numbers of patients who showed similar results, which led to their recommendation that "neuroimaging is a recommended part of the diagnostic evaluation," particularly should there be abnormal findings on examination (ie, microcephaly, macrocephaly, focal motor findings, pyramidal signs, extrapyramidal signs) and that MRI is preferable to CT. However, the authors of the American College of Medical Genetics Consensus Conference Report¹⁰ stated that neuroimaging by CT or MRI in normocephalic patients without focal neurologic signs should not be considered a "standard of

TABLE 4 Common Recognizable XLID Syndromes

Syndrome	Common Manifestations	Gene, Location
Aarskog syndrome	Short stature, hypertelorism, downslanting palpebral fissures, joint hyperextensibility, shawl scrotum	<i>FGD1</i> , Xp11.21
Adrenoleukodystrophy	Variable and progressive vision and hearing loss, spasticity, neurological deterioration associated with demyelination of the central nervous system and adrenal insufficiency	<i>ABCD1</i> , Xq28
Aicardi syndrome	Agenesis of the corpus callosum, lacunar chorioretinopathy, costovertebral anomalies, seizures in females	_____, Xp22
Allan–Herndon syndrome	Generalized muscle hypoplasia, childhood hypotonia, ataxia, athetosis, dysarthria, progressing to spastic paraplegia	<i>MCT8</i> (SLC16A2), Xq13
ARX-related syndromes (includes Partington, Proud, West, XLAG syndromes and nonsyndromal XLMR)	Partington: dysarthria, dystonia, hyperreflexia, seizures. West: infantile spasms, hypsarrhythmia. Proud: microcephaly, ACC, spasticity, seizures, ataxia, genital anomalies. XLAG: lissencephaly, seizures, genital anomalies	<i>ARX</i> , Xp22.3
ATRX syndrome (includes ARTX, Chudley–Lowry, Carpenter–Waziri, Holmes–Gang, and Martinez spastic paraplegia syndromes and nonsyndromal XLMR)	Short stature, microcephaly, hypotonic facies with hypertelorism, small nose, open mouth and prominent lips, brachydactyly, genital anomalies, hypotonia, in some cases hemoglobin H inclusions in erythrocytes	<i>XNP</i> , (XH2) Xq13.3
Christianson syndrome	Short stature, microcephaly, long narrow face, large ears, long straight nose, prominent mandible, general asthenia, narrow chest, long thin digits, adducted thumbs, contractures, seizures, autistic features, truncal ataxia, ophthalmoplegia, mutism, incontinence, hypoplasia of the cerebellum, and brain stem	<i>SLC9A6</i> , Xq26
Coffin–Lowry syndrome	Short stature, distinctive facies, large soft hands, hypotonia, joint hyperextensibility, skeletal changes	<i>RSK2</i> , Xp22
Creatine transporter deficiency	Nondysmorphic, autistic, possibly progressive	<i>SLC6A8</i> , Xq28
Duchenne muscular dystrophy	Pseudohypertrophic muscular dystrophy	<i>DMD</i> , Xp21.3
Fragile X syndrome	Prominent forehead, long face, recessed midface, large ears, prominent mandible, macroorchidism	<i>FMR1</i> , Xq27.3
Hunter syndrome	Progressive coarsening of face, thick skin, cardiac valve disease, joint stiffening, dysostosis multiplex	<i>IDS</i> , Xq28
Incontinentia pigmenti	Sequence of cutaneous blistering, verrucous thickening, and irregular pigmentation. May have associated CNS, ocular abnormalities	<i>NEMO</i> (IKB6KG), Xq28
Lesch–Nyhan syndrome	Choreoathetosis, spasticity, seizures, self-mutilation, uric acid urinary stones	<i>HPRT</i> , Xq26
Lowe syndrome	Short stature, cataracts, hypotonia, renal tubular dysfunction	<i>OCRL</i> , Xq26.1
MECP2 duplication syndrome	Hypotonia, progressing to spastic paraplegia, recurrent infections	<i>MECP2</i> , Xq28
Menkes syndrome	Growth deficiency, full cheeks, sparse kinky hair, metaphyseal changes, limited spontaneous movement, hypertonicity, seizures, hypothermia, lethargy, arterial tortuosity, death in early childhood	<i>ATP7A</i> , Xp13.3
Pelizaeus–Merzbacher disease	Nystagmus, truncal hypotonia, progressive spastic paraplegia, ataxia, dystonia	<i>PLP</i> , Xq21.1
Renpenning syndrome (includes Sutherland–Haan, cerebropalatocardiac, Golabi–Ito–Hall, Porteous syndrome)	Short stature, microcephaly, small testes. May have ocular or genital abnormalities	<i>PQBPI</i> , Xp11.3
Rett syndrome	XLMR in girls, cessation and regression of development in early childhood, truncal ataxia, autistic features, acquired microcephaly	<i>MECP2</i> , Xq28
X-linked hydrocephaly-MASA spectrum	Hydrocephalus, adducted thumbs, spastic paraplegia	<i>L1CAM</i> , Xq28

Reproduced with permission from Stevenson and Schwartz.⁴⁶

practice” or mandatory and believed that decisions regarding “cranial imaging will need to follow (not precede) a thorough assessment of the patient and the clinical presentation.” In contrast, van Karnebeek et al¹² found that

MRI alone leads to an etiologic diagnosis in a much lower percentage of patients studied. They cited Kjos et al,⁷² who reported diagnoses in 3.9% of patients who had no known cause for their ID and who did not manifest either

a progressive or degenerative course in terms of their neurologic symptomatology. Bouhadiba et al⁷³ reported diagnoses in 0.9% of patients with neurologic symptoms, and in 4 additional studies, no etiologic or syndromic

diagnosis on the basis of neuroimaging alone was found.^{65,69,74,75} The authors of 3 studies reported the results on unselected patients; Majnemer and Shevell⁶⁷ reported a diagnosis by this typed unselected investigation in 0.2%, Stromme⁷⁶ reported a diagnosis in 1.4% of patients, and van Karnebeek et al⁴⁰ reported a diagnosis in 2.2% of patients.

Although a considerable evolution has occurred over the past 2 decades in neuroimaging techniques and modalities, for the most part with the exception of proton magnetic resonance spectroscopy, this has not been applied or reported in the clinical situation of developmental delay/ID in childhood. Proton resonance spectroscopy provides a noninvasive mechanism of measuring brain metabolites, such as lactate, using technical modifications to MRI. Martin et al⁷⁷ did not detect any differences in brain metabolite concentrations among stratifications of GDD/ID into mild, moderate, and severe levels. Furthermore, they did not detect any significant differences in brain metabolite concentration between children with GDD/ID and age-matched typically developing control children. Thus, these authors concluded that proton resonance spectroscopy “has little information concerning cause of unexplained DD.” Similarly, the studies by Martin et al⁷⁷ and Verbruggen et al⁷¹ did not reveal that proton magnetic resonance spectroscopy was particularly useful in the determination of an underlying etiologic diagnosis in children with unexplained developmental delay/ID.

All of these findings suggest that abnormal findings on MRI are seen in ~30% of children with developmental delay/ID. However, only in a fraction of these children does MRI lead to an etiologic or syndromic diagnosis. The precise value of a negative MRI result in leading to a diagnosis has not yet

been studied in detail. In addition, MRI in the young child with developmental delay/ID invariably requires sedation or, in some cases, anesthesia to immobilize the child to accomplish the imaging study. This need, however, is decreasing with faster acquisition times provided by more modern imaging technology. Although the risk of sedation or anesthesia is small, it still merits consideration within the decision calculus for practitioners and the child's family.^{63,78,79} Thus, although MRI is often useful in the evaluation of the child with developmental delay/ID, at present, it cannot be definitively recommended as a mandatory study, and it certainly has higher diagnostic yields when concurrent neurologic indications exist derived from a careful physical examination of the child (ie, microcephaly, macrocephaly, seizures, or focal motor findings).

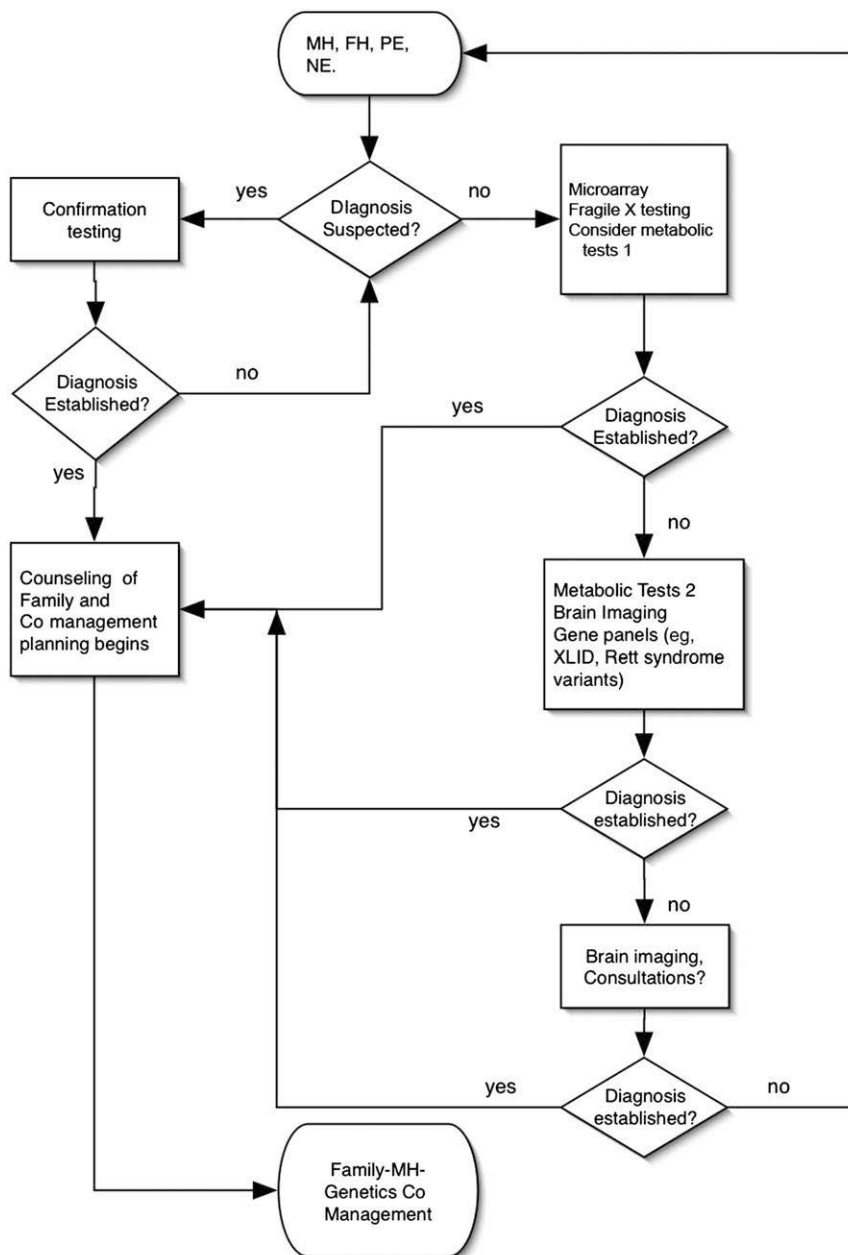
RECOMMENDED APPROACH

The following is the recommended medical genetic diagnostic evaluation flow process for a new patient with GDD/ID. All patients with ID, irrespective of degree of disability, merit a comprehensive medical evaluation coordinated by the medical home in conjunction with the medical genetics specialist. What follows is the clinical genetics evaluation (Fig 1):

1. Complete medical history; 3-generation family history; and physical, dysmorphicologic, and neurologic examinations.
2. If the specific diagnosis is certain, inform the family and the medical home, providing informational resources for both; set in place an explicit shared health care plan⁸⁰ with the medical home and family, including role definitions; provide sources of information and support to the family; provide genetic counseling services by a certified genetic counselor; and discuss

treatment and prognosis. Confirm the clinical diagnosis with the appropriate genetic testing, as warranted by clinical circumstances.

3. If a specific diagnosis is suspected, arrange for the appropriate diagnostic studies to confirm including single-gene tests or chromosomal microarray test.
4. If diagnosis is unknown and no clinical diagnosis is strongly suspected, begin the stepwise evaluation process:
 - a. Chromosomal microarray should be performed in all.
 - b. Specific metabolic testing should be considered and should include serum total homocysteine, acyl-carnitine profile, amino acids; and urine organic acids, glycosaminoglycans, oligosaccharides, purines, pyrimidines, GAA/creatine metabolites.
 - c. Fragile X genetic testing should be performed in all.
5. If no diagnosis is established:
 - a. Male gender and family history suggestive X-linkage, complete XLID panel that contains genes causal of nonsyndromic XLID and complete high-density X-CMA. Consider X-inactivation skewing in the mother of the proband.
 - b. Female gender: complete *MECP2* deletion, duplication, and sequencing study.
6. If microcephaly, macrocephaly, or abnormal findings on neurologic examination (focal motor findings, pyramidal signs, extrapyramidal signs, intractable epilepsy, or focal seizures), perform brain MRI.
7. If brain MRI findings are negative or normal, review status of diagnostic evaluation with family and medical home.
8. Consider referrals to other specialists, signs of inborn errors of metabolism

**FIGURE 1**

Diagnostic process and care planning. Metabolic test 1: blood homocysteine, acylcarnitine profile, amino acids; and, urine organic acids, glycosaminoglycans, oligosaccharides, purines, pyrimidines, GAA/creatine metabolites. Metabolic test 2 based on clinical signs and symptoms. FH, family history; MH, medical history; NE, neurologic examination; PE, physical and dysmorphology examination.

for which screening has not yet been performed, etc.

9. If no further studies appear warranted, develop a plan with the family and medical home for needed services for child and family; also develop a plan for diagnostic reevaluation.

THE SHARED EVALUATION AND CARE PLAN FOR LIMITED ACCESS

Health care systems, processes, and outcomes vary geographically, and not all of what is recommended in this clinical report is easily accessible in all regions of the United States.^{21,81–84} Consequently, local factors affect the

process of evaluation and care. These arrangements are largely by local custom or design. In some areas, there may be quick access and intimate coordination between the medical home and medical genetics specialist, but in other regions, access may be constrained by distance or by decreased capacity, making for long wait times for appointments. Some general pediatricians have the ability to interpret the results of genetic testing that they may order. In addition, children with GDD or ID are often referred by pediatricians to developmental pediatricians, child neurologists, or other subspecialists. It is appropriate for some elements of the medical genetic evaluation to be performed by physicians other than medical geneticists if they have the ability to interpret the test results and provide appropriate counseling to the families. In such circumstances, the diagnostic evaluation process can be designed to address local particularities. The medical home is responsible for referrals of the family and child to the appropriate special education or early developmental services professional for individualized services. In addition, the medical home can begin the process of the diagnostic evaluation if access is a problem and in coordination with colleagues in medical genetics.^{80,85} What follows is a suggested process for the evaluation by the medical home and the medical genetics specialist and only applies where access is a problem; any such process is better established with local particularities in mind:

Medical home completes the medical evaluation, determines that GDD/ID is present, counsels family, refers to educational services, completes a 3-generation family history, and completes the physical examination and addresses the following questions:

1. Does the child have abnormalities on the dysmorphologic examination?

- a. If no or uncertain, obtain microarray, perform fragile X testing, and consider the metabolic testing listed previously. Confirm that newborn screening was completed and reported negative. Refer to medical genetics while testing is pending.
 - b. If yes, send case summary and clinical photo to medical genetics center for review for syndrome identification. If diagnosis is suspected, arrange for expedited medical genetics referral and hold all testing listed above. Medical geneticist to arrange visit with genetic counselor for testing for suspected condition.
2. Does the child have microcephaly, macrocephaly, or abnormal neurologic examination (listed above)? If "yes," measure parental head circumferences and review the family history for affected and unaffected members. If normal head circumferences in both parents and negative family history, obtain brain MRI and refer to medical genetics.
 3. Does child also have features of autism, cerebral palsy, epilepsy, or sensory disorders (deafness, blindness)? This protocol does not address these patients; manage and refer as per local circumstances.
 4. As above are arranged and completed and negative, refer to medical genetics and hold on additional diagnostic testing until consultation completed. Continue with current medical home family support services and health care.
 5. Should a diagnosis be established, the medical home, medical geneticist, and family might then agree to a care plan with explicit roles and responsibilities of all.
 6. Should a diagnosis not be established by medical genetics consultation, the medical home, family, and

medical geneticist can then agree on the frequency and timing of diagnostic reevaluation while providing the family and child services needed.

EMERGING TECHNOLOGIES

Several research reports have cited whole-exome sequencing and whole-genome sequencing in patients with known clinical syndromes for whom the causative gene was unknown. These research reports identified the causative genes in patients with rare syndromes (eg, Miller syndrome,⁸⁶ Charcot-Marie-Tooth disease,⁸⁷ and a child with severe inflammatory bowel disease⁸⁸). Applying similar whole-genome sequencing of a family of 4 with 1 affected individual, Roach et al⁸⁶ identified the genes for Miller syndrome and primary ciliary dyskinesia. The ability to do whole-genome sequencing and interpretation at an acceptable price is on the horizon.^{87,89} The use of exome or whole-genome sequencing challenges the field of medical genetics in ways not yet fully understood. When a child presents with ID and whole-genome sequencing is applied, one will identify mutations that are unrelated to the question being addressed, in this case "What is the cause of the child's intellectual disability?" One assumes that this will include mutations that families do not want to have (eg, adult-onset disorders for which no treatment now exists). This is a sea change for the field of medical genetics, and the implications of this new technology have not been fully explored. In addition, ethical issues regarding validity of new tests, uncertainty, and use of resources will need to be addressed as these technologies become available for clinical use.^{90,91}

CONCLUSIONS

The medical genetic diagnostic evaluation of the child with GDD/ID is best accomplished in collaboration with the medical home and family by using this

clinical report to guide the process. The manner in which the elements of this clinical protocol are applied is subject to local circumstances, as well as the decision-making by the involved pediatric primary care provider and family. The goals and the process of the diagnostic evaluation are unchanged: to improve the health and well-being of those with GDD/ID. It is important to emphasize the new role of the genomic microarray as a first-line test, as well as the renewal of efforts to identify the child with an inborn error of metabolism. The future use of whole-genome sequencing offers promise and challenges needing to be addressed before regular implementation in the clinic.

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Contraception for Adolescents

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- *Policy Statement*

POLICY STATEMENT

Contraception for Adolescents

abstract

FREE

Contraception is a pillar in reducing adolescent pregnancy rates. The American Academy of Pediatrics recommends that pediatricians develop a working knowledge of contraception to help adolescents reduce risks of and negative health consequences related to unintended pregnancy. Over the past 10 years, a number of new contraceptive methods have become available to adolescents, newer guidance has been issued on existing contraceptive methods, and the evidence base for contraception for special populations (adolescents who have disabilities, are obese, are recipients of solid organ transplants, or are HIV infected) has expanded. The Academy has addressed contraception since 1980, and this policy statement updates the 2007 statement on contraception and adolescents. It provides the pediatrician with a description and rationale for best practices in counseling and prescribing contraception for adolescents. It is supported by an accompanying technical report. *Pediatrics* 2014;134:e1244–e1256

INTRODUCTION

Pediatricians play an important role in adolescent pregnancy prevention and contraception. Nearly half of US high school students report ever having had sexual intercourse.¹ Each year, approximately 750 000 adolescents become pregnant, with more than 80% of these pregnancies unplanned, indicating an unmet need for effective contraception in this population.^{2,3} Although condoms are the most frequently used form of contraception (52% of females reported condom use at last sex), use of more effective hormonal methods, including combined oral contraceptives (COCs) and other hormonal methods, was lower, at 31% and 12%, respectively, in 2011.¹ Use of highly effective long-acting reversible contraceptives, such as implants or intrauterine devices (IUDs), was much lower.¹

Adolescents consider pediatricians and other health care providers a highly trusted source of sexual health information.^{4,5} Pediatricians' long-term relationships with adolescents and families allow them to ask about sensitive topics, such as sexuality and relationships, and to promote healthy sexual decision-making, including abstinence and contraceptive use for teenagers who are sexually active. Additionally, medical indications for hormonal contraception, such as dysmenorrhea, heavy menstrual bleeding or other abnormal uterine bleeding, acne, and polycystic ovary syndrome, are often uncovered during adolescent visits. A working knowledge of contraception will assist the pediatrician in both sexual health promotion and treatment of common

COMMITTEE ON ADOLESCENCE

KEY WORDS

contraception, adolescent, birth control, intrauterine device, contraceptive implant, oral contraceptive pills, contraceptive injection

ABBREVIATIONS

AAP—American Academy of Pediatrics
ACOG—American College of Obstetricians and Gynecologists
BMD—bone mineral density
CDC—Centers for Disease Control and Prevention
COC—combined oral contraceptive
DMPA—depot medroxyprogesterone acetate
EC—emergency contraception
FDA—Food and Drug Administration
HIPAA—Health Insurance Portability and Accountability Act
IUD—intrauterine device
LARC—long-acting reversible contraception
PID—pelvic inflammatory disease
STI—sexually transmitted infection

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adolescent gynecologic problems. Contraception has been inconsistently covered as part of insurance plans. However, the Institute of Medicine has recommended contraception as an essential component of adolescent preventive care,⁶ and the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111–148) requires coverage of preventive services for women, which includes contraception, without a copay.^{7,8}

SETTING THE STAGE

Confidentiality and Consent

In the setting of contraception and sexual health care, the American Academy of Pediatrics (AAP) believes that policies supporting adolescent consent and protecting adolescent confidentiality are in the best interests of adolescents. Accordingly, best practice guidelines recommend confidentiality around sexuality and sexually transmitted infections (STIs) and minor consent for contraception.^{9–11} The majority of states have specific laws regarding minor consent to contraception (see *State Minor Consent Laws: A Summary*¹² and the Guttmacher Institute's State Center¹³ at <http://www.guttmacher.org/statecenter/> for regularly updated state-by-state summaries). For states without specific laws, best practice guidelines, federal statutes, and federal case law may support minor confidentiality and consent.¹² For example, family planning clinics funded by Title X of the federal Public Health Services Act (42 USC §§300–300a-6 [1970]) are required to provide confidential services to adolescents.¹²

The Health Insurance Portability and Accountability Act (HIPAA [Pub L No. 104–191, 1996]) specifically addresses minor confidentiality. Although HIPAA allows parents access to a minor's records as personal representatives, that access is denied when the minor is provided with confidentiality under state or other laws or when the parent agrees that the minor may have confidential

care.¹⁴ Therefore, the AAP recommends that pediatricians have an office policy that explicitly describes confidential services and that pediatricians discuss (and document) confidentiality with all parents and adolescents. As an additional protection for minors' confidentiality, HIPAA states that if there is no applicable state law about the rights of parents to access the protected health information of their children, pediatricians (or other licensed health professionals) may exercise their professional judgment to provide or deny parental access to the records.¹⁴ This can be accomplished with careful documentation of their professional judgment. Insurance, billing, and electronic health record systems create additional challenges, including maintaining the confidentiality of visits, visit content, associated laboratory test results, and payment for the contraceptive method itself.¹⁵ For additional discussion of electronic health records, see the AAP policy statement on health information technology.¹⁶

Careful attention to minor consent and confidentiality is important, because limitations on confidentiality and consent are linked to lower use of contraceptives and higher adolescent pregnancy rates.^{17–21} Parents need not be adversaries; in fact, many parents are supportive of minor consent and confidentiality for sexual health services.^{22,23} As permitted by law, adolescent contraception should be provided as a confidential service, with adolescents encouraged to involve parents or trusted adults as they are able.

Sexual History Taking and Counseling

Bright Futures recommends that pediatricians take a developmentally targeted sexual history, assess STI and pregnancy risk, and provide appropriate screening, counseling, and, if needed, contraceptives.²⁴ Key to history taking is an

honest, caring, nonjudgmental attitude and a comfortable, matter-of-fact approach to asking questions. This can be accomplished by assessing the 5 Ps of sexual history taking, as described by the Centers for Disease Control and Prevention (CDC): partners, prevention of pregnancy, protection from STIs, sexual practices, and past history of STIs and pregnancy.²⁵ Counseling should draw on motivational interviewing approaches, with the focus of the interview on future goals, belief in the adolescents' capacity to change, and engagement of the adolescent in the process of adopting health-promoting behaviors.²⁶ For an example of motivational interviewing for sexual health counseling, see Ott et al (2007),²⁷ and for a more detailed discussion of counseling approaches, see the accompanying technical report.²⁸

Counseling About Abstinence and Contraception

Counseling about abstinence and postponement of sexual intercourse is an important aspect of adolescent sexual health care. Abstinence is 100% effective in preventing pregnancy and STIs and is an important part of contraceptive counseling. Adolescents should be encouraged to delay sexual onset until they are ready. However, existing data suggest that, over time, perfect adherence to abstinence is low (ie, many adolescents planning on abstinence do not remain abstinent).^{29,30} Therefore, pediatricians should not rely on abstinence counseling alone but should additionally provide access to comprehensive sexual health information to all adolescents. For sexually active adolescents, including gay and lesbian adolescents,³¹ and those considering initiation of sexual activity, counseling additionally includes initiating contraception, supporting adherence to the contraceptive method, managing adverse effects, and providing periodic screening for STIs.²⁴

METHODS OF CONTRACEPTION

This section summarizes the contraceptive options for adolescents; the accompanying technical report provides more detailed information on each of the methods. When comparing the efficacy of different methods, it is important to distinguish between typical use and perfect use, and counseling should be based on typical use. Typical use efficacy refers to the probability of pregnancy during the first year of typical use and includes users with varying degrees of adherence; perfect use efficacy is the probability of pregnancy if used consistently and correctly every time.³² The most effective methods rely the least on individual adherence; for these methods, typical use effectiveness approaches perfect use effectiveness. Contraceptive methods most commonly used by adolescents are listed below, ordered from most to least effective, starting with long-acting reversible contraception (LARC): implants and IUDs. *Pediatricians are encouraged to counsel adolescents in that order, discussing the most effective contraceptive methods first* (see Table 1 for contraceptive effectiveness).

Progestin Implants

Implanon and Nexplanon (Merck, Whitehouse Station, NJ) are both single-rod implants that contain etonogestrel, the active metabolite of the progestin desogestrel. Implants, a LARC method, are highly effective, with typical and perfect use failure rates of less than 1%^{32,33}; they may remain in place for 3 years. The implant is inserted into the inside of the upper arm by a clinician who has completed the requisite training. Implants are ideal for adolescents who prefer a method that does not require regularly scheduled adherence and who desire an extended length of protection. A common reason for discontinuation is unpredictable bleeding or spotting.^{34,35}

TABLE 1 Contraceptive Method Efficacy

Method	% of Women Experiencing an Unintended Pregnancy in the First Year of Use		% of Women Continuing Use at 1 Year ^a
	Typical Use ^b	Perfect Use ^c	
No method	85	85	—
Spermicides (foams, creams, gels, suppositories, and film)	28	18	42
Fertility awareness–based methods	24	—	47
Withdrawal	22	4	46
Condom			
Female	21	5	41
Male	18	2	43
Diaphragm	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Contraceptive patch	9	0.3	67
Contraceptive ring	9	0.3	67
DMPA contraceptive injection	6	0.2	56
IUD			
Copper T	0.8	0.6	78
Levonorgestrel	0.2	0.2	80
Single-rod contraceptive implant	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

—, data not available.

^a Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 y.

^b Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth, corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

^c Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

Contraceptive implants can also be offered to pregnant adolescents and provided in the immediate postpartum period, while the adolescent is still in the hospital. The American College of Obstetricians and Gynecologists (ACOG) and the CDC both support immediate postpartum insertion of implants as a safe and effective practice that removes barriers to care.^{36,37} The main theoretical concern about contraceptive implant use in the postpartum period is whether the progestin might have some effect on breastfeeding; however, studies of contraceptive implant use among breastfeeding women have generally found no effects on breastfeeding performance or infant health and growth.^{38,39} When starting an implant, patients should be counseled that a backup method (ie, condoms or abstinence) should be used for at least

the first week for contraceptive efficacy and that a condom should be used at all times for protection against STIs.

IUDs

IUDs inserted into the uterus also provide long-acting reversible contraception. Three IUDs currently are approved in the United States: 2 levonorgestrel-releasing T-shaped IUDs (Mirena, 52 mg levonorgestrel, and Skyla, 13.5 mg levonorgestrel; Bayer HealthCare Pharmaceuticals Inc, Wayne, NJ) and a copper-containing T-shaped IUD (Copper T380-A, ParaGard; Teva North America, North Wales, PA). The 13.5-mg levonorgestrel IUD is approved for 3 years,⁴⁰ the 52-mg levonorgestrel IUD is approved for 5 years,⁴¹ and the copper IUD is approved for 10 years.⁴² Despite their low but increasing use in the United

States, IUDs are used extensively worldwide because they are safe and effective methods of contraception with typical and perfect use failure rates of less than 1%.⁴³ The copper IUD can be used as emergency contraception (EC) within 5 days of unprotected intercourse.^{43,44}

Despite past concerns, IUDs are now known to be safe for nulliparous adolescents. IUDs themselves do not cause tubal infertility in nulliparous women,⁴⁵ and studies support a rapid return to fertility after IUD removal.^{46,47} The risk of pelvic infection with IUDs occurs only during insertion. Beyond the first 21 days, IUDs do not increase rates of STIs or pelvic inflammatory disease (PID).^{48,49} Unless the adolescent is at very high risk for STIs (eg, had sex with a partner with known gonorrhea), screening for gonorrhea and chlamydia can be performed on the day of insertion.⁵⁰ Treatment, if needed, can be subsequently provided without IUD removal, because studies have demonstrated that, provided the patient improves with treatment, both STIs and PID can be treated with the IUD in place.^{51,52} Contraindications to IUD placement are limited to current purulent cervicitis, gonorrhea, or chlamydia, current PID and other current pelvic infections (see “US Medical Eligibility Criteria for Contraceptive Use” for more extensive discussion).³⁷ Past PID is not a contraindication to IUD use. HIV infection and immunosuppression are also not contraindications to IUD use.

IUDs can also be offered to pregnant adolescents and provided in the immediate postpartum period, while the adolescent is still in the hospital. Two systematic reviews concluded that immediate postpartum insertion of IUDs is safe and effective,^{53,54} and both ACOG and the CDC support this practice.^{36,37,55} Studies have shown that many women who desire an IUD at the time of delivery do not return for later insertion and

that immediate insertion of IUDs provides similar contraceptive coverage as delayed insertion, even with higher expulsion rates with immediate insertion.^{56,57}

The emerging adolescent-specific data on IUDs are promising. However, there are some disadvantages. The limited data in adolescents suggest that expulsion, which occurs in fewer than 5% of women using IUDs, may occur more frequently in younger women.⁵⁸ Another concern is that more than half of young nulliparous women report moderate to severe pain with insertion.^{59,60} Nonetheless, studies demonstrate IUD continuation rates in adolescents that exceed those with other hormonal methods and effective use of the levonorgestrel IUD for menstrual suppression in adolescent patients with complex medical conditions.^{61–67}

Progestin-Only Injectable Contraception

Depot medroxyprogesterone acetate (DMPA, also known by the brand name Depo-Provera; Pfizer, New York, NY) is a long-acting progestin that is given as a single injection every 13 weeks (up to 15 weeks) using a dose of either 150 mg delivered intramuscularly or 104 mg delivered subcutaneously. Many health care providers schedule visits every 11 to 12 weeks for adolescents to allow for missed or delayed visits. Both regimens have similar effectiveness and side effects⁶⁸ and are highly effective in preventing pregnancy. In the first year of use, the probability of becoming pregnant with typical use is approximately 6%.³² DMPA can be initiated on the same day as the visit (“mid-cycle” or “quick” start) as long as the health care provider is reasonably certain the adolescent is not pregnant. For additional details, see the accompanying technical report and the CDC’s 2013 “US Selected Practice Recommendations for Contraceptive

Use.”⁵² When starting DMPA, patients should be counseled that a backup method (eg, condoms or abstinence) should be used for at least the first week for contraceptive efficacy and that a condom should be used at all times for protection against STIs.

DMPA is convenient for many adolescents because of its ease of use. Other advantages include improvement in dysmenorrhea and protection against iron deficiency anemia and endometrial cancer.⁶⁹ DMPA is safe for most patients with chronic illness,³⁷ is thought to raise the seizure threshold in adolescents with epilepsy,⁷⁰ and may decrease sickle cell crises.^{71,72}

The major disadvantages of DMPA include the need for an injection every 13 weeks and the menstrual cycle irregularities that are present for nearly all patients initially. These menstrual irregularities typically improve over time^{73,74} and may be less likely to result in discontinuation if patients are counseled about these effects before the first injection.^{75,76} Other possible adverse effects include headache, mastalgia, hair loss, change in libido, and weight gain. Studies in both adolescents⁷⁷ and adults⁷⁸ suggest that weight gain status at 6 months is a strong predictor of future excessive weight gain with ongoing DMPA use, but that weight gain does not occur in all patients.^{79,80}

DMPA causes reductions in bone mineral density (BMD),^{81–83} and in 2004 the US Food and Drug Administration (FDA) issued a black-box warning about the risk of decreased BMD among DMPA users.⁸⁴ Subsequent publications document a substantial recovery of BMD after the patient discontinues DMPA,^{85–87} and ACOG, recognizing the risk of unwanted pregnancy if women’s contraceptive options are limited, does not advise limiting DMPA use to 2 years (in contrast to earlier concerns⁸⁸) or routinely monitoring bone density after that time frame.⁸⁹ Nonetheless, it remains

important to consider other risk factors for osteoporosis and to tailor counseling and recommendations to each patient. All patients should be counseled about measures that promote skeletal health, such as daily intake of 1300 mg of calcium and 600 IU of vitamin D and regular weight-bearing exercise.⁹⁰

Combined Oral Contraceptive Pills

COCs are the most popular method of hormonal contraception for adolescents. COCs all contain a progestin and an estrogen. In almost every pill, the estrogen component is ethinyl estradiol in amounts varying from 10 to 50 µg. Many adolescent medicine experts begin with a COC containing 30 to 35 µg of ethinyl estradiol and a progestin such as levonorgestrel or norgestimate. However, any “low-dose” pill (ie, containing ethinyl estradiol 35 µg or less) can be used. Although inspection of the external genitalia and a vaginal swab or urine screen for STIs are recommended practices in the care of sexually active patients,⁹¹ no gynecologic examination is needed to determine eligibility for COC use. Like other combined methods including the contraceptive vaginal ring and transdermal patch, COCs can be started on the same day as the visit (“quick start”) in healthy, nonpregnant adolescents. Patients should be counseled that a backup method (ie, condoms or abstinence) should be used for at least the first 7 days for contraceptive efficacy and that a condom should be used at all times for protection against STIs. The CDC recommends prescribing up to 1 year of COCs at a time.⁵² Additionally, a routine follow-up visit 1 to 3 months after initiating COCs is useful for addressing adverse effects or adherence issues.

COCs have few contraindications in healthy female adolescents. They should not be prescribed for patients with severe and uncontrolled hypertension (systolic pressure ≥ 160 mm Hg or

diastolic pressure ≥ 100 mm Hg), ongoing hepatic dysfunction, complicated valvular heart disease, migraines with aura or focal neurologic symptoms, thromboembolism or thrombophilia, complications of diabetes (ie, nephropathy, retinopathy, neuropathy, or other vascular disease), and complicated solid organ transplantation.³⁷ The most serious adverse event associated with COC use is the increased risk of blood clots, which increases from 1 per 10 000 to 3 to 4 per 10 000 woman-years during COC use.^{92,93} In comparison, the incidence of venous thromboembolism associated with pregnancy and postpartum is 10 to 20 per 10 000 woman-years, of which 1% to 2% are fatal.^{94,95} Although smoking should be discouraged, it is not a contraindication to COC use in teenagers and adults younger than 35 years old.³⁷

Patients should be informed that common transient adverse effects of COCs include irregular bleeding, headache, and nausea. Recommendations for managing adverse effects have been published elsewhere⁹⁶ or can be found online (<http://www.managingcontraception.com/qa/index.php> or http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w).⁵² Drug interactions should also be avoided. With medications that decrease COC effectiveness (eg, anti-convulsants and antiretroviral drugs), patients may benefit from choosing an alternative method or dosing⁹⁷ (see the accompanying technical report for additional details). Most broad-spectrum antibiotics (rifampin is an exception) do not affect the contraceptive effectiveness of COCs.³⁷

Typical use failure rates are 9% in adults and may be higher in adolescents.^{32,98} Counseling should include strategies to promote daily adherence, such as cell phone alarms and support from a family member or partner. Patients should be instructed

on what to do if pills are missed. A missed pill should be taken as soon as it is remembered. If more than 1 pill in a row is missed, only the most recently missed pill should be taken as soon as possible, and the remaining pills should be taken at the usual time. Patients should be reminded that 7 consecutive hormone pills are needed to prevent ovulation. Additional instructions can be accessed online (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w#Fig2).⁵² EC is indicated if 2 or more pills are missed in the first week of the cycle.^{99,100} EC should also be considered if 1 or more pills were missed earlier in the same cycle as a missed pill or late in the previous cycle (see online instructions provided earlier for details).

Many patients may benefit from decreasing or eliminating the hormone-free (placebo) interval. Extended or continuous cycles may be useful for treating medical conditions such as anemia, acne, severe dysmenorrhea, endometriosis, dysfunctional or heavy menstrual bleeding, Von Willebrand disease, and other bleeding diatheses and for adolescents who prefer amenorrhea.¹⁰¹ These regimens may also be useful for conditions that can be exacerbated cyclically, such as migraine (without aura), epilepsy, irritable bowel syndrome, inflammatory bowel disease, and some psychiatric and behavioral symptoms¹⁰²; the most common adverse effect of extended or continuous cycles is unscheduled bleeding. Patients may be reassured to know that observational data indicate that COC use does not increase the risk of infertility or breast cancer¹⁰³ and that use of COCs for more than 4 years provides significant protection against endometrial and ovarian cancers.¹⁰⁴

Contraceptive Vaginal Ring

The vaginal ring (NuvaRing; Merck, Whitehouse Station, NJ) releases a combination

of estrogen and progestin and thus has the same eligibility criteria for use as COCs. As with COCs, a same-day start (“quick start”) can also be used with the vaginal ring. The ring is inserted in the vagina and stays in place for 3 weeks, with removal for 1 week to induce withdrawal bleeding, followed by insertion of a new ring. Patients should be instructed to insert a new ring after 7 days even if bleeding has not ceased.

The ring has comparable efficacy, risks, and benefits as other combined hormonal methods but provides the simplest regimen.^{32,105,106} Adverse effects are also similar, with the additional vaginal symptoms of discharge, discomfort, and problems related to the device (eg, expulsion).¹⁰⁷ The ring is an excellent method for extended use because, although labeled for 28 days of use, the rings contain sufficient medication to be used for up to 35 days¹⁰⁸ and thus can be replaced once every calendar month. Sexually active patients may be reassured to know that most men were not bothered by its presence, if it was noted at all.^{109,110}

Transdermal Contraceptive Patch

The combination hormone (estrogen and progestin) transdermal contraceptive patch (Ortho Evra; Ortho-McNeil Pharmaceutical, Raritan, NJ) is placed on the abdomen, upper torso, upper outer arm, or buttocks using 1 patch for each of 3 weeks in a row, followed by 1 week off the patch, during which a withdrawal bleed usually occurs. Typical use failure rates are similar to those of COCs at 9%.³² The FDA has identified increased estrogen exposure (1.6 times higher than with a low-dose COC¹¹¹) and a potential increased risk of venous thromboembolism with the patch^{112,113} (see accompanying technical report for more complete discussion).

The patch has comparable efficacy, benefits, eligibility criteria for use, and drug interactions as COCs; side effects are similar to those of other combined methods, with the addition of dislodged patches and skin effects, such as hyperpigmentation,^{114,115} contact dermatitis, and other irritation.¹¹⁶ The risk of pregnancy with correct (“perfect”) use of the patch is slightly higher for women who weigh more than 198 pounds than for women who weigh less (0.9% vs 0.3% in first 12 months of use).^{117,118}

Progestin-Only Pills

Progestin-only pills (also known as “mini-pills”) work primarily by thickening cervical mucus, not by inhibiting ovulation. Because very stringent adherence is necessary, their failure rate can be significantly higher than those of other combined hormonal and progestin-only methods (IUDs and contraceptive implants and injections). However, they provide an additional option for patients who have safety concerns about estrogen use (see accompanying technical report for additional details).³⁷

Male Condoms

The male condom is the most common contraceptive method used by adolescents, with up to 52% of female and 75% of male adolescents reporting condom use at last intercourse.¹ Advantages include male involvement in the responsibility for contraception, easy accessibility by minors without a prescription, and low cost. Latex condoms also reduce STI transmission, with consistent evidence for the reduction of gonorrhea, chlamydia, trichomoniasis,^{119–123} and hepatitis B and HIV transmission¹²⁴ and emerging evidence for the reduction of herpes simplex virus,^{125,126} human papillomavirus,^{127,128} and syphilis transmission.¹²⁹ However, condom use requires com-

mitment at every sex act, tends to drop off over time, and is influenced by individual, relationship, and broader social factors.^{130–133} Although the perfect use failure rate of condoms is 2%, the typical use failure rate is 18% for all users and can be higher among adolescents.³² The high typical use failure rate, coupled with the condom's high STI protection, has led to the recommendation for dual contraception: condoms plus a highly effective hormonal or other long-acting method. Instructions for condom use can be found in the accompanying technical report, and additional details are provided in the AAP policy statement on condoms.¹³³

Emergency Contraception

In the United States, EC is available as oral levonorgestrel; an oral progesterone receptor modulator; ulipristal acetate; high-dose combined estrogen–progestin oral contraceptive pills (the Yuzpe regimen); and placement of a copper IUD. Levonorgestrel EC is preferred to the Yuzpe regimen because of the superior adverse effect profile and effectiveness, which is up to 85%.^{44,134} Ulipristal acetate may have greater effectiveness than oral levonorgestrel at the end of the 5-day window of use, and its remaining effectiveness and adverse effect profile are similar to those of levonorgestrel.^{135,136} In addition, on the basis of recent data about lower efficacy of levonorgestrel EC, ulipristal may be more effective in people who weigh more than 165 pounds.^{137,138} Placement of a copper-bearing IUD is less commonly used for EC in adolescents but is the most effective EC method, with a failure rate of less than 1%.¹³⁹

The recommended dosage of levonorgestrel is a single 1.5-mg dose.^{134,140} It is available either as 2 pills (0.75 mg each) or as 1 pill (Plan B One-Step; Teva Pharmaceuticals, Petah Tikva, Israel). Levonorgestrel-based EC delays or inhibits ovulation and does not

appear to be effective once ovulation has occurred. If used inadvertently during early pregnancy, it is not teratogenic, only ineffective.¹⁴¹ Thus, a pregnancy test is not mandatory before levonorgestrel EC is prescribed.⁴⁴

Plan B One-Step is approved by the FDA as a nonprescription product for all women of childbearing potential.¹⁴² Generic versions are approved as a nonprescription product for women 17 years of age and older; however, proof of age is not required to purchase them. Providing EC in advance increases the likelihood of use when it is needed without increasing sexual or contraceptive risk-taking behavior.^{143,144} Therefore, EC should be prescribed or recommended in advance for use for up to 5 days after an event of unprotected intercourse.⁴⁴ Additional details on EC mechanisms and use can be found in the AAP policy statement on emergency contraception⁴⁴ and the accompanying technical report.

Withdrawal

Withdrawal, or coitus interruptus, is a method in which the male partner attempts to pull out his penis before ejaculation. Because 57% of female adolescents report using withdrawal,¹ pediatricians should ask about it. However, because of its limited effectiveness (22% failure rate among all users)³² and lack of STI protection, pediatricians should encourage adolescents to adopt more effective methods.

Other Methods

The female condom, periodic abstinence (fertility awareness or “the rhythm method”), vaginal spermicides, the cervical cap, and the diaphragm are methods less commonly used by adolescents. Additional descriptions are available in the accompanying technical report.

SPECIAL POPULATIONS

Adolescents With Disabilities and Medically Complex Illness

An estimated 16% to 25% of adolescents are identified as having special health care needs, including physical disability, developmental disability, and medically complex illness.¹⁴⁵ The improved survival of adolescents with medically complex illnesses, such as disabilities, chronic disease, HIV, and solid organ transplants, has prompted greater attention to quality-of-life issues. These issues, including adolescent interest in romantic and sexual relationships, are typically addressed by a pediatrician. Sexuality and sexual health care needs in this population are often overlooked, yet data demonstrate that, compared with healthy adolescents, adolescents with chronic illness have similar levels of sexual behaviors and sexual health outcomes (eg, STIs).^{146,147} In addition to pregnancy prevention, these adolescents may need menstrual suppression for heavy menstrual bleeding, bleeding disorders, or chemotherapy. Other patients may be using teratogenic medications and need contraception for that reason. Issues that arise include safety concerns with estrogen use, medication interactions, and complications from the underlying disease. The CDC has recently addressed the contraceptive needs of young women with medical conditions by publishing the “US Medical Eligibility Criteria for Contraceptive Use.”³⁷ Available online, this document summarizes the literature on safety and efficacy of different contraceptive methods by medical condition. Additional details on specific populations (eg, those with disabilities) are summarized in the accompanying technical report.

Adolescents With Obesity

The sexual health needs and sexual behaviors of adolescents with obesity are substantially similar to those of

their normal-weight peers.^{148,149} In addressing contraception, it is important to note that obesity and related endocrine effects can influence the efficacy and adverse effects profiles of contraceptives. For example, a small number of excess pregnancies were found among transdermal contraceptive patch users weighing more than 90 kg (198 lb).^{117,118} The World Health Organization and CDC report that data are limited and inconsistent about whether COC effectiveness varies by body weight or BMI.^{37,150–152} A common concern of both adolescents and providers is additional weight gain among adolescents with obesity after they start contraception. Data suggest that women with obesity are no more likely to gain weight with COCs, the vaginal ring, IUDs, or implants than normal-weight peers. In contrast, adolescents with obesity who used DMPA were more likely than nonusers with obesity, COC users with obesity, and normal-weight DMPA users to gain weight.⁸⁰

Increasing numbers of adolescents are having bariatric surgery procedures performed, and these patients need highly effective contraception. Post-surgery data reveal an improvement in fertility coupled with the potential for decreased contraceptive effectiveness through malabsorption, vomiting, and diarrhea.⁸⁶ Professional consensus statements recommend delaying pregnancy for at least 12 months after the procedure.¹⁵³ All contraceptive methods are safe for women with a history of bariatric surgery, with the exception of oral contraceptives for women who have undergone malabsorptive procedures.³⁷ There is increasing experience and success with the levonorgestrel IUD placed at the time of surgery.¹⁵⁴

ADHERENCE AND FOLLOW-UP

Frequent follow-up is important to maximize adherence for all methods of contraception and to promote and

reinforce healthy decision-making. Adolescents count on trusted health professionals, such as pediatricians, for support and problem solving around continuation and adherence. Regularly scheduled contraceptive follow-up visits should address use, adherence, adverse effects, and complications. Pediatricians can use motivational interviewing approaches to increase effective and consistent contraceptive use, including engaging parental support for contraceptive adherence, when possible. Follow-up visits should additionally include reassessment of relationships, sexual behaviors, contraceptive needs, STI surveillance and prevention, and other sexual health prevention measures, such as human papillomavirus immunization.

RECOMMENDATIONS

1. Pediatricians should counsel about and ensure access to a broad range of contraceptive services for their adolescent patients. This includes educating patients about all contraceptive methods that are safe and appropriate for them and describing the most effective methods first.
2. Pediatricians should be able to educate adolescent patients about LARC methods, including the progestin implant and IUDs. Given the efficacy, safety, and ease of use, LARC methods should be considered first-line contraceptive choices for adolescents. Some pediatricians may choose to acquire the skills to provide these methods to adolescents. Those who do not should identify health care providers in their communities to whom patients can be referred.
3. Despite increased attention to adverse effects, DMPA and the contraceptive patch are highly effective methods of contraception that are much safer than pregnancy. Pediatricians should continue to make them available to their patients.

tricians should continue to make them available to their patients.

4. Pediatricians should allow the adolescent to consent to contraceptive care and to control the disclosure of this information within the limits of state and federal laws. There are a number of supports for protecting minor consent and confidentiality, including state law, federal statutes, and federal case law. Pediatricians will need to be familiar with national best practice recommendations for confidential care and with the relevant minor consent laws in their states.
5. Pediatricians should be aware that it is appropriate to prescribe contraceptives or refer for IUD placement without first conducting a pelvic examination. Screenings for STIs, especially chlamydia, can be performed without a pelvic examination and should not be delayed.
6. Pediatricians should encourage the consistent and correct use of condoms with every act of sexual intercourse.
7. Pediatricians should have a working knowledge of the different combined hormonal methods and regimens, because these provide excellent cycle control both for contraception and medical management of common conditions, such as acne, dysmenorrhea, and heavy menstrual bleeding.
8. Pediatricians should remember that adolescents with chronic illness and disabilities have similar sexual health and contraceptive needs to healthy adolescents while recognizing that medical illness may complicate contraceptive choices.
9. Pediatricians should regularly update their adolescent patients' sexual histories and provide a confidential and nonjudgmental setting in which to

address needs for contraception, STI screening, and sexual risk reduction counseling for patients who choose not to be abstinent.

10. Pediatricians should allow sufficient time with their adolescent patients to address contraceptive needs using a developmentally appropriate, patient-centered approach, such as motivational interviewing. If necessary, arrangements should be made for a separate visit for contraceptive follow-up to increase adherence and monitor for adverse effects and complications.
11. Pediatricians can complement the skills and resources of the pediatric office by being aware of state or federally subsidized insurance programs and clinics that provide confidential and free or low-cost reproductive health care services and supplies, including contraception.

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Contraception for Adolescents

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- *Technical Report*

TECHNICAL REPORT

Contraception for Adolescents

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KEY WORDS

contraception, adolescent, birth control, intrauterine device, contraceptive implant, oral contraceptive pills, contraceptive injection

ABBREVIATIONS

AAP—American Academy of Pediatrics
ART—antiretroviral therapy
BMD—bone mineral density
CDC—Centers for Disease Control and Prevention
COC—combined oral contraceptive
DMPA—depot medroxyprogesterone acetate
EC—emergency contraception
FDA—US Food and Drug Administration
HIPAA—Health Insurance Portability and Accountability Act
IUD—intrauterine device
LARC—long-acting reversible contraception
POP—progestin-only pill
STI—sexually transmitted infection
VTE—venous thromboembolism

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abstract

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A working knowledge of contraception will assist the pediatrician in both sexual health promotion as well as treatment of common adolescent gynecologic problems. Best practices in adolescent anticipatory guidance and screening include a sexual health history, screening for pregnancy and sexually transmitted infections, counseling, and if indicated, providing access to contraceptives. Pediatricians' long-term relationships with adolescents and families allow them to help promote healthy sexual decision-making, including abstinence and contraceptive use. Additionally, medical indications for contraception, such as acne, dysmenorrhea, and heavy menstrual bleeding, are frequently uncovered during adolescent visits. This technical report provides an evidence base for the accompanying policy statement and addresses key aspects of adolescent contraceptive use, including the following: (1) sexual history taking, confidentiality, and counseling; (2) adolescent data on the use and side effects of newer contraceptive methods; (3) new data on older contraceptive methods; and (4) evidence supporting the use of contraceptives in adolescent patients with complex medical conditions. *Pediatrics* 2014;134:e1257–e1281

INTRODUCTION

Pediatricians play a key role in adolescent sexual health and contraception. Sexual health is an important part of adolescent anticipatory guidance and screening, and pediatricians' long-term relationships with adolescents and families allow them to help promote healthy sexual decision-making, including abstinence and contraceptive use. Additionally, medical indications for contraception, such as acne, dysmenorrhea, and heavy menstrual bleeding, are frequently uncovered during adolescent visits. A working knowledge of contraception will assist the pediatrician in both sexual health promotion as well as treatment of common adolescent gynecologic problems. This technical report provides the pediatrician with updated information on adolescent sexual behavior, guidelines for counseling adolescents, and an update on available methods of contraception. It is a companion to the policy statement "Contraception for Adolescents."¹

ADOLESCENT SEXUAL BEHAVIOR AND USE OF CONTRACEPTION

Sexual intercourse is common among adolescents. In 2011, 47% of high school students reported ever having had sex, and 34% reported having had sex in the previous 3 months.² For the pediatrician, this means that approximately half of their adolescent patients have engaged in sex,

many without adequate protection against pregnancy and sexually transmitted infections (STIs).

Unintended pregnancy is a serious adolescent morbidity, and use of effective contraception is one of the pillars of adolescent pregnancy prevention. Each year, approximately 750 000 adolescent girls become pregnant, and 82% of these pregnancies are unplanned.^{3,4} More than half of these pregnancies (59%) end in births, 14% end in miscarriages, and 27% end in abortion.³ From 1990 to the early 2000s, adolescent pregnancy rates declined markedly, and 86% of this decline was attributable to increased consistent contraceptive use (the remainder was attributed to delay of sexual activity).⁵ By 20 years of age, 18% of young women will have given birth, and this number is largely unchanged from 2002.⁶

The contraceptive method most commonly used by adolescents is the condom (96% of young women who have ever used a contraceptive reported previous condom use), followed by withdrawal (57%) (see Table 1). Among hormonal methods, experience with combined oral contraceptives (COCs) is most common (56%), followed by depot medroxyprogesterone acetate

(DMPA) injection (20%), the transdermal patch (10%), and the vaginal ring (5%). More than 13% of adolescents have ever used emergency contraception (EC), and 15% have ever used periodic abstinence. However, ever having used a method does not necessarily translate into consistent or current use. When a nationally representative sample of all 15- to 19-year-old adolescent girls were asked about current use (past 3 months), 28% reported any contraceptive use. The pill was most commonly used (15%), followed by condoms (6%), DMPA (3%), and withdrawal, the contraceptive ring, and the intrauterine device (IUD) (all approximately 1%). The transdermal patch was less than 1% (see Table 2). Experience with long-acting reversible contraception (LARC), such as IUDs and implants, has increased markedly in 15- to 19-year-olds over the past decade, with the bulk of the increase in the 18- to 19-year age range. By 2009, it was estimated that 4.5% of contraceptive use was an IUD or implant.⁴

SETTING THE STAGE: CONFIDENTIALITY, CONSENT, AND THE SEXUAL HISTORY

Sexual history taking and counseling about pregnancy prevention, including contraceptive use, are key Bright Futures objectives for the adolescent visit.⁷ The demands of these tasks can be managed by situating them in an adolescent's medical home. Because of pediatricians' ongoing relationships with adolescents and families, they are optimally suited for this role.⁷ The following sections outline the evidence base for key elements relevant to contraceptive care, including confidentiality and consent, sexual history taking, and counseling.

Confidentiality and Consent

In the setting of contraception and sexual health care, the American Academy of

Pediatrics (AAP) believes that policies supporting adolescent consent and protecting adolescent confidentiality are in the best interests of adolescents. Most states have specific laws regarding minor consent to contraception (see "State Minor Consent Laws: A Summary"⁸ and the Guttmacher Institute's State Center⁹ for regularly updated state-by-state summaries). For states without specific laws, best-practices guidelines, federal statutes, and federal case law may support minor confidentiality and consent.¹⁰ For example, family-planning clinics funded by Title X of the federal Public Health Services Act (42 USC §§300–300a-6 [1970]) are required to provide confidential services to adolescents.⁸

The Health Insurance Portability and Accountability Act (HIPAA [Pub L No. 104-191, 1996]) specifically addresses minor confidentiality. Although HIPAA allows parents access to adolescents' records as personal representatives of the minor, that access is denied when the minor can consent under state or other laws, or when the parent agrees that the minor may have confidential care.¹⁰ The AAP, therefore, recommends that pediatricians have an office policy that explicitly describes confidential services and that pediatricians discuss (and document) confidentiality with all parents and adolescents. As an additional protection for minors' confidentiality, HIPAA states that if there is no applicable state law about the rights of parents to access the protected health information of their children, pediatricians (or other licensed health professionals) may exercise their professional judgment to provide or deny parental access to the records. This can be accomplished with careful documentation of their professional judgment.

Insurance billing, electronic health record systems, and patient portals create additional challenges to maintaining the

TABLE 1 Lifetime Use (Ever-Use) of Contraception Among Sexually Experienced Women Aged 15 to 19 Years: United States, 2006 to 2010

Method	% Distribution
Any method ¹⁸⁸	98.9
Injectable	20.3
Pill	55.6
Contraceptive patch	10.3
Contraceptive ring	5.2
Emergency contraception	13.7
Condom	95.8
Female condom	1.5
Periodic abstinence—calendar	15.0
Withdrawal	57.3
Other methods	7.1
Long-acting reversible contraceptives (IUDs and implants) ⁶⁴	4.5

TABLE 2 Current Contraceptive Use by Method of Women Aged 15 to 19 Years: United States, 2006 to 2008¹⁶²

Contraceptive Status and Method	% Distribution
Using contraception	28.2
Pill	15.2
Implant, Lunelle, or patch	0.5
3-mo injectable (Depo-Provera)	2.6
Contraceptive ring	1.0
IUD	1.0
Condom	6.4
Withdrawal	1.1
Not using contraception	71.8
Nonsurgically sterile—female or male	0.5
Pregnant or postpartum	3.9
Seeking pregnancy	0.9
Other nonuse:	
Never had intercourse or no intercourse in 3 mo before interview	60.0
Had intercourse in 3 mo before interview	6.5

confidentiality of visits, visit content, and associated laboratory testing that will need to be considered. The AAP policy statement on electronic health records supports privacy policies consistent with state health care consent laws and best practices around sensitive health topics such as sexual behavior and contraception.¹¹

Importance of Confidentiality and Consent

Careful attention to minor consent and confidentiality are important, because confidentiality is a major concern of adolescents¹² and a reason for foregoing contraceptive care. In a nationally representative sample, adolescents most in need of confidential health services (eg, sexually active girls) were more likely to cite confidentiality as a reason for foregoing health care.¹³ Confidentiality concerns are heightened among adolescents from underrepresented minority groups^{14,15} and other groups at high risk of unintended pregnancy (eg, those involved with the juvenile justice system; lesbian, bisexual, and transgender; and lower-income youth).^{16,17} Many adolescents

are unaware they can obtain confidential health care,¹⁸ presenting a potential barrier to access to contraceptive services.

Limitations on adolescents' confidentiality and their ability to consent have been associated with lower use of contraceptive services and poor outcomes. Among minors attending family-planning clinics, young women reported that if parental notification were required for prescriptive contraceptives, only 1% would stop having vaginal sex, but 59% would stop using all clinic services.¹⁹ Among young African American women, fear of family finding out about sexual health services was a common reason to delay a first clinic visit for contraception.²⁰ On a population level, minors' capacity to consent to contraceptives has been associated with lower adolescent birth rates,²¹ and restrictions on minors' capacity to consent to contraceptives have been associated with higher birth rates.²²

Parents

The relationship among parents, confidentiality, and access is complex. Many parents are supportive of minor consent and confidentiality for sexual health services. In a national Internet-based survey, 66% of parents agreed that it was important for adolescents to have private time with physicians, and more than half (54%) of parents did not want doctors to disclose confidential information obtained from adolescents to parents.²³ Many parents are aware that their adolescents use confidential sexual health services. A national study of adolescent family-planning clinic clients revealed that 60% of adolescents reported that their parents were aware of their use of sexual health services.²⁴ Among adolescents whose parents were aware of their sexual health service use, 79% would continue to use the services, even if parental notification were required; however, among adolescents

whose parents were unaware of their sexual health services use, fewer than 30% would continue to use services.²⁴

Sexual History Taking and Counseling

Taking a Sexual History

Adolescents consider pediatricians and other health care providers a highly trusted source of sexual health and other confidential information.^{25,26} When pediatricians discuss sensitive topics with adolescents, instead of reporting discomfort, adolescents reported that the pediatrician understood their problems, eased their worries, and allowed them to make treatment decisions.²⁷ Best-practices guidelines require that the sexual history be taken with the adolescent alone.⁷ Key to history taking is an honest, caring, nonjudgmental attitude and a comfortable, matter-of-fact approach to asking questions. This can be accomplished by using the "5 Ps" tool of the Centers for Disease Control and Prevention (CDC): partners, prevention of pregnancy, protection from STIs, sexual practices, and past history of STIs and pregnancy (see <http://www.cdc.gov/std/treatment/SexualHistory.pdf>).²⁸

Contraceptive counseling should be developmentally targeted, because the sexual health and contraceptive needs of early adolescents differ markedly from those of middle and late adolescents. Even among same-age adolescents, there is often a wide range in adolescents' sense of themselves as a sexual being, their sexual experiences, and their interest and need for contraception. For example, a study of early adolescents described views and behaviors ranging from considering sex to be "nasty" and something best left to adults, to an intense curiosity about and initiation of sexual behaviors.²⁹ Bright Futures provides sample questions and guidance for a developmentally tailored sexual history.⁷

Counseling Using Motivational Interviewing

Increasing evidence from studies of adolescents suggests that individual counseling about contraception and sexual health topics is most effective using patient-centered approaches, such as motivational interviewing.^{30,31} Motivational interviewing can be used to address the ambivalence and discrepancies among adolescents' sexual and contraceptive behaviors, their sexual and relationship values, and future life goals. Key elements are (1) an empathetic and nonjudgmental interviewer with unconditional positive regard for the adolescent in a safe, nonthreatening environment; (2) engaging adolescents in their own behavior change; (3) asking adolescents about their goals, and helping them identify inconsistencies between their goals and current behavior; (4) "rolling with resistance," or avoiding direct confrontation when resistance is met, and waiting for adolescents to find their own answers rather than pointing them out; and (5) supporting adolescents' capacity to change.^{32,33} Motivational interviewing is a natural extension of youth development principles in its focus on goals and future orientation, belief in adolescents' capacity to change, and engagement of adolescents in the process of adopting health-promoting behaviors.³⁴

Motivational interviewing is accomplished through open-ended questions and careful listening.^{32,33} In the context of pregnancy prevention and sexual health promotion, discussions might explore the adolescent's reasons for becoming sexually active and the effect that sexual intercourse and unintended pregnancy may have on relationships with peers, parents, and significant others.³⁵ For example, does the adolescent believe that sex will deepen a relationship?³⁶ Or is sexual behavior or pregnancy considered a

marker for adulthood?³⁷ A motivational interviewing approach to contraceptive counseling might also focus on adolescents' goals (examples of goals linked to sexual decision-making include school completion, college, marriage, and childbearing³⁷), and how contraception and the delay of pregnancy might affect those goals.³⁵ An example of an inconsistency between goals and behaviors might be the adolescent who expresses a desire to graduate from high school and attend college but is frequently engaging in unprotected sex, putting her at risk for an unintended pregnancy.

A common concern of pediatricians is giving complex messages to adolescents: in the case of sexual behavior, the complex message is that a pediatrician would like to encourage abstinence but also is willing and able to provide appropriate counseling regarding sexuality and contraception. With motivational interviewing approaches, it is possible and appropriate for pediatricians to provide this type of complex message, because the focus is on the adolescents' values and relationships and related goals and discrepancies between goals and behaviors. Research suggests that adolescents are capable of understanding this type of complex message and, in fact, may disregard messages that they consider judgmental or overly simplified or that eliminate key health information.^{25,26} More detailed information on motivational interviewing with adolescents can be found in recent publications.^{35,38}

Abstinence Counseling in the Office Setting

Counseling about abstinence is an important component of sexual health care. When used consistently without exception, abstinence can be an effective means of contraception and STI prevention and is a viable strategy in the pediatrician's toolkit for reducing unintended pregnancy and STIs. It has

been estimated that approximately one-quarter of the decline in the adolescent pregnancy rates from 1995 to 2002 was attributable to the delayed initiation of sexual activity.⁵ Abstinence counseling should follow the motivational interviewing approaches described previously. A set of practical tips for abstinence counseling within an office-based setting has been published, and it uses a comprehensive motivational interviewing perspective.³⁵

When adhered to perfectly, sexual abstinence is 100% effective, making it an attractive choice for pregnancy prevention. However, many adolescents who practice abstinence do not adhere to the method 100% of the time (ie, they occasionally have vaginal-penile intercourse). Few data exist on actual effectiveness of abstinence (called "typical use," see explanation in *Methods of Contraception*)³⁹; however, existing data suggest that the effectiveness of abstinence for pregnancy and STI prevention over extended periods of time is likely low. For example, among adolescents reporting virginity pledges in the National Longitudinal Study of Adolescent Health, at 6-year follow-up (wave 3), 88% had engaged in sexual intercourse (most premarital), and 5% were infected with STIs.⁴⁰ Because of concerns about a low typical-use effectiveness of abstinence as a contraceptive method, it is critical for pediatricians to reassess intentions to remain abstinent at every visit and additionally to provide access to comprehensive sexual health information, including information about EC and condom use. Comprehensive information, including pregnancy prevention, should be provided to all adolescents, including those who identify as lesbian and gay, because they may have opposite-sex partners as well.¹⁷

METHODS OF CONTRACEPTION

Numerous reviews and recommendations for prescribing and managing

contraception are available (see, for example, *Contraceptive Technology*⁴¹ and the CDC's "US Selected Prescribing Recommendations for Contraceptive Use"⁴²). Additionally, there are online resources for prescribing contraceptives geared toward clinicians (see Table 3). The following section focuses on the appropriateness of various methods available for adolescents.

When comparing the efficacy of different contraceptive methods, it is important to distinguish "perfect use" and "typical use." Perfect-use efficacy refers to the probability of pregnancy if used consistently and correctly every time; data for perfect use come from clinical trials with very high levels of adherence.⁴³ Typical-use efficacy refers to the probability of pregnancy during the first year of typical use; data for typical-use efficacy come from national surveys that include users with varying degrees of adherence.⁴³ Thus, the typical-use efficacy rates reflect how well a contraceptive method works with an average user, factoring in mistakes, such as missed pills, forgotten condoms, or patches that are left on too long. Table 4 includes perfect- and typical-use data for all contraceptive methods. The individual methods appropriate for adolescents are addressed hereafter, discussed in order of effectiveness, starting with LARC. It is recommended that pediatricians use a "tiered" approach to contraceptive counseling, starting with the most effective methods.

Progestin Implants

Currently available progestin implant LARC methods include Implanon and Nexplanon (Merck, Whitehouse Station, NJ). Both consist of a single-rod implant that contains etonogestrel, the active metabolite of desogestrel; Nexplanon also contains barium sulfate to render it visible on radiography. The implant, highly effective with a failure rate of less than 1%,^{43,44} may remain in place for 3 years. It is inserted into the inside of the nondominant upper arm, 6 to 8 cm above the elbow, by a medical professional who has completed the requisite training. Insertion takes approximately 1 minute, and removal can be accomplished in under 5 minutes.⁴⁵ Complications are rare but include transient nerve injury and the need for removal under general anesthesia.^{44,46,47} Implants are ideal for adolescents who prefer a method that does not require regularly scheduled adherence and who desire an extended length of protection. Authors in Brazil have identified it as a viable option for delaying second pregnancy in adolescent mothers.⁴⁸ In Australia, a prospective study was conducted of 137 adolescent mothers, 18 years or younger.⁴⁹ Participants selected their own method, with half choosing the implant and the remainder choosing COCs, DMPA, a barrier method, or nothing. Both method continuation and time to next pregnancy were significantly longer in implant users. It must be noted, however, that there were key differences be-

tween the users of the implant and users of other methods. For example, implant users were significantly more likely to be living with the birth father rather than one of their own parents. In addition, more than half of implant users discontinued their method earlier than 24 months, with the most common reason being abnormal uterine bleeding. This is consistent with observational studies (as opposed to clinical trials, which tend to enroll and retain more adherent contraception users) describing continuation rates and bleeding patterns in adult users.^{50,51} In a published summary of 11 clinical trials that included a total of 942 women within 80% to 130% of their ideal body weight, 64% reported amenorrhea or infrequent bleeding over the first 2 years, and 15% reported frequent or prolonged bleeding.⁵² This may differ from clinicians' anecdotal experience in part because heavier women may have more bleeding than lighter women.⁵³ Unlike most other continuous methods, it is not clear that implant users experience improved bleeding patterns over time.⁵⁴ Experience in the first 3 months may help predict future bleeding patterns,⁵³ but individual experience is highly variable. Although bleeding is frequent with all progestin-only methods, it is important to remember that unscheduled bleeding can also be a sign of an STI, and adolescents should be tested accordingly. Data are limited, but experts have recommended the use of nonsteroidal anti-inflammatory drugs and/or COCs

TABLE 3 Online Contraceptive and Sexual Health Resources for Providers

Centers for Disease Control and Prevention	
US Selected Practice Recommendations for Contraceptive Use, 2013	http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w
Counseling Resources: Teen Pregnancy Prevention	http://www.cdc.gov/teenpregnancy/healthcareproviders.htm
US Medical Eligibility Criteria for Contraceptive Use, 2010	www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf
<i>Contraceptive Technology</i>	http://www.contraceptivetechnology.org/reproductive-health-resources/training-videos-slides/
Association of Reproductive Health Professionals Web site	www.arph.org/
Managing Contraception	www.managingcontraception.com/ga
World Health Organization Medical Eligibility for Contraceptive Use	http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf
Princeton University Emergency Contraception Web site	ec.princeton.edu/

TABLE 4 Contraceptive Method Efficacy

Method	% of Women Experiencing an Unintended Pregnancy Within the First Year of Use		% of Women Continuing Use at 1 Year ^c
	Typical Use ^a	Perfect Use ^b	
No method	85	85	—
Spermicides (foams, creams, gels, suppositories, and film,)	28	18	42
Fertility awareness-based methods	24	—	47
Withdrawal	22	4	46
Condom			
Female	21	5	41
Male	18	2	43
Diaphragm	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Contraceptive patch	9	0.3	67
Contraceptive ring	9	0.3	67
DMPA injection	6	0.2	56
IUD			
Copper T	0.8	0.6	78
Levonorgestrel	0.2	0.2	80
Single-rod contraceptive implant	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

—, data not available.

Source: Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83(5):397–404.

^a Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth, corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

^b Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason.

^c Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

as potentially helpful measures to manage implant-related bleeding.⁵⁴

Other than irregular bleeding, adverse effects are not common, but include emotional lability, weight gain, headache, and acne.⁵² Data are scant on the effect of the implant on bone mineral density (BMD).^{55–57} Given the higher estradiol level in implant users compared with DMPA users,⁵⁴ it could be presumed that the implant has less effect on BMD, but this has not been adequately assessed in adolescent women. Similar to the combined hormonal methods, efficacy is impaired by hepatic enzyme-inducing drugs (see Table 5); however, implants are considered safe for women with estrogen contraindications.⁵⁸

For adolescents who need highly effective contraception that is user- and coitus-independent, the implant is an

outstanding choice. However, it is critical that the risk of persistent irregular bleeding is well understood; to date, this is the most common complaint resulting in premature removal. For adolescents seeking hormonal methods specifically to manage abnormal uterine bleeding and irregular cycles, a combined method or a levonorgestrel IUD may be more acceptable to the patient.

Intrauterine Contraception

IUDs are inserted into the uterus to provide long-acting reversible contraception. Appropriate for adolescents, IUDs are generally safe, effective methods of contraception with a failure rate of less than 1% (see Table 4).⁴³ Three IUDs currently are approved for the US market: a copper-containing T-shaped IUD (copper T380-A, ParaGard; Teva

North America, North Wales, PA) and 2 levonorgestrel-releasing T-shaped IUDs (52-mg levonorgestrel, Mirena, and 13.5-mg levonorgestrel, Skyla; Bayer HealthCare Pharmaceuticals Inc, Wayne, NJ). The primary mechanism of action of both types of IUD is preventing fertilization by inhibiting sperm motility. The levonorgestrel IUDs also thicken cervical mucus. All mechanisms occur before implantation, when pregnancy begins, and inhibiting implantation is not believed to be a primary mechanism of action for either type of IUD.⁵⁹ The 13.5-mg levonorgestrel IUD is approved for 3 years.⁶⁰ The 52-mg levonorgestrel IUD is approved for 5 years,⁶¹ although data suggest that it is still effective at least up to 7 years; similarly, the copper T380-A IUD is approved for 10 years,⁶² but data support use for 12 years.⁶³ Although IUDs have very low use in the United States, they are used extensively worldwide, and use is increasing in the United States, particularly among older adolescents.⁶⁴

Previous concerns about adolescents and IUDs have been addressed by more recent data demonstrating that IUDs are safe for nulliparous adolescents. For example, a case-control study demonstrated that past associations between infertility and IUD use among nulliparous women were attributable to STIs rather than IUDs.⁶⁵ Other studies support a rapid return to fertility after IUD removal.^{66,67} Data also address concerns about pelvic infections. There is a small increase in infection risk around the time of IUD insertion as a result of the procedure. However, beyond the first 20 days after insertion, IUDs do not increase rates of pelvic inflammatory disease (PID) above baseline.^{68,69} Screening for gonorrhea and *Chlamydia* can be performed at the same time as insertion.⁵⁹ Any necessary treatment can be subsequently provided without IUD removal, as international studies have demonstrated that STIs

TABLE 5 Medications That Decrease COC Efficacy

Antibiotics
Rifampin
Anticonvulsants
Felbamate
Ethosuximide
Primidone
Phenobarbital
Phenytoin (Dilantin)
Carbamazepine
Oxcarbazepine
Lamotrigine ^a
Rufinamide ^a
Topiramate
Antidepressants
St. John's wort ^{b,c}

Source: World Health Organization. *Medical Eligibility Criteria for Contraceptive Use*. 4th ed. Geneva, Switzerland: World Health Organization; 2009.

^a Fewer data are available for these newer antiepileptic drugs, but available data suggest they can decrease COC effectiveness.

^b Advantages of COC use generally outweigh the risks.

^c Murphy PA, Kern SE, Stanczyk FZ, Westhoff CL. Interaction of St. John's Wort with oral contraceptives: effects on the pharmacokinetics of norethindrone and ethinyl estradiol, ovarian activity and breakthrough bleeding. *Contraception*. 2005;71(6):402-408.

and PID can be treated with the IUD in place,⁷⁰ as long as the patient improves with treatment. As a result, there are now more limited infectious contraindications to IUDs. These include current or recent (past 3 months) PID or current gonorrhea, *Chlamydia*, or purulent cervicitis. Additional contraindications include pregnancy and uterine anomalies that distort the uterine cavity in a manner incompatible with IUD insertion (see CDC recommendations for complete list⁵⁸). HIV infection and immunosuppression are not contraindications to IUD use.

The one area with less clarity is that, for insertion of IUDs (but not continuation), "high risk of STIs" is considered by the CDC to be level 2 (benefits generally outweigh risks) or level 3 (risks generally outweigh benefits, but clinician may individualize). However, the data supporting the level 3 categorization are from a study of HIV-infected adult women in Africa.⁵⁸ Beyond STI risk, existing concerns about IUD use in adolescents are that rates of expulsions

and experiences of pain and discomfort are somewhat higher among nulliparous compared with parous young women. Nonetheless, current data suggest that IUDs are generally well tolerated in young women and that continuation and satisfaction rates are high.⁷¹⁻⁷⁴

Adolescent-specific data are limited on acceptability and use of IUDs for contraception; however, recent studies are promising, suggesting 1-year continuation rates of 75% or greater.⁷⁵⁻⁷⁸ The data on levonorgestrel IUD use for medical indications in adolescents reveal improvement in dysmenorrhea and heavy menses.^{76,79} The levonorgestrel IUD is also useful for adolescents with medical conditions that require long-term menstrual suppression in which estrogen is contraindicated or that present a serious risk to the fetus in the case of unintended pregnancy. For example, use of the levonorgestrel IUD with disabled nonambulatory adolescents allows effective menstrual suppression while avoiding both exogenous estrogen exposure and the bone-density effects of DMPA.^{78,80} Levonorgestrel IUDs also provide an important option for adolescent bariatric surgery patients, for whom experts recommend a delay of pregnancy of at least 12 to 18 months after surgery but who often experience a rapid return to fertility after surgery.⁸¹ Barriers to pediatricians inserting IUDs, such as lack of training, lack of office capacity, or not seeing enough patient volume to maintain skills, pose an access problem, which can be overcome by identifying specific providers in the community to whom these patients can be referred.

Progestin Injections

DMPA, also known by the brand name Depo-Provera (Pfizer, New York, NY) is a long-acting progestin that is given as a single injection every 13 weeks (up to 15 weeks) using a dose of either 150 mg

delivered intramuscularly or 104 mg delivered subcutaneously; the feasibility of self-administration of the latter is currently under investigation. Both regimens have similar effectiveness and side effects.⁸² DMPA can be initiated on the same day as the visit ("mid-cycle" or "quick" start). The CDC states that even if pregnancy cannot be definitively ruled out, the benefits of initiating DMPA exceed the risks and that DMPA can be initiated at any time, with a follow-up pregnancy test in 2 to 4 weeks.⁴²

DMPA is highly effective in preventing pregnancy. In the first year of use, the probability of becoming pregnant by typical users is approximately 6% (perfect use is 0.2%; see Table 4).⁴³ Some experts believe that the use of DMPA, which first became available in the United States in 1992, is one factor responsible for the declining rates of adolescent pregnancy in the United States.^{5,83}

DMPA is convenient for many adolescents because of its ease of use compared with coitus-dependent methods or those that require daily, weekly, or monthly adherence. Other advantages, similar to combined hormonal methods, include improvement in dysmenorrhea and protection against iron-deficiency anemia and endometrial cancer.⁸⁴ DMPA may be safely recommended for adolescents who are lactating⁸⁵ and most of those who have chronic illnesses.⁵⁸ It may provide additional benefits in some circumstances, for example, by raising the seizure threshold⁸⁵ and decreasing sickle cell crises.^{87,88} Despite recent work suggesting that DMPA may result in an increased risk of venous thrombosis,⁸⁹ for patients at risk for estrogen-related complications, the advantages of DMPA are still believed to outweigh the risks.⁵⁸

The major disadvantages of DMPA for adolescents are menstrual cycle irregularities (present for nearly all patients initially), the need for an

injection every 13 weeks, and potential adverse effects, including weight gain and interference with normal increases in bone density. Other adverse effects include headache, mastalgia, hair loss, and change in libido. Although rare, anaphylaxis to DMPA has been described.⁹⁰

The irregular bleeding associated with DMPA typically improves over time.^{91,92} Studies have demonstrated that patients are more likely to continue DMPA use if they are counseled about adverse effects before their first injection, but these studies did not target adolescents specifically.^{93,94} Long-term DMPA use is also associated with a delayed return to fertility, typically 9 to 18 months, while the endometrial lining returns to its pre-DMPA state and ovulatory function returns. Both subcutaneous and intramuscular DMPA show similar delays to fertility after injection.⁹⁵ However, for adolescent patients, such a delay does not usually pose a major deterrent to using this method.

Although a number of observational studies have found an increased risk of weight gain among young women using DMPA,^{96–100} a recent Cochrane review¹⁰¹ evaluated this subject and identified only 2 high-quality and 2 moderate-quality studies, only one of which¹⁰² demonstrated that adolescents using DMPA had increased body fat percentage and decreased lean body mass. This finding, in contrast to widespread clinical observations about significant weight gain with DMPA, could be explained by significant variability in the trajectories of weight gain among women using DMPA. Bonny et al¹⁰³ studied 97 adolescents and found that 21% experienced early weight gain, defined as an increase in weight of more than 5% at 6 months. Over 18 months, those early gainers experienced an increase in mean BMI of 7.6 compared with 2.3 for non-early

weight gainers. Similar findings in adult patients¹⁰⁴ suggest that weight-gain status at 6 months is a strong predictor of future excessive weight gain with ongoing DMPA use but that weight gain on DMPA is not a uniform finding for all patients.^{96,98}

Because DMPA suppresses circulating estradiol concentrations, it causes lack of BMD accrual^{105–107} and has an adverse effect on biochemical markers of bone formation and resorption.¹⁰⁸ In response to these concerns, the Food and Drug Administration (FDA) issued a “black-box” warning regarding the risk of decreased BMD among DMPA users in November 2004.¹⁰⁹ The warning recommended using DMPA for longer than 2 years only if other methods are inadequate, noting a lack of certainty regarding peak BMD attained later in life among users of DMPA. Since that time, 3 publications have described prospective studies of adolescent and young adult women during and after use of DMPA.^{110–112} All 3 documented substantial recovery of BMD after DMPA use, thus, offering reassurance about the long-term skeletal health of adolescent patients who use DMPA. The American College of Obstetricians and Gynecologists, recognizing the risk of unwanted pregnancy if adolescents’ contraceptive options are limited, does not advise limiting DMPA use to 2 years, nor does it recommend monitoring BMD after that time frame.⁸³ In addition, some experts¹¹³ dispute the limited data that suggest a link between DMPA use and elevated risk of fractures in reproductive-age women^{114,115} and have called for removal of the black box warning.

Although recent studies are reassuring about the likelihood of bone recovery after DMPA cessation, it is important to consider other risk factors for osteoporosis and to tailor counseling and recommendations to each patient. Factors such as small

body habitus, chronic alcohol or tobacco use, eating disorders, or illness that necessitates chronic use of corticosteroids may lead a clinician to more strongly encourage alternatives to DMPA. All patients should be encouraged to include foods and/or supplements to ensure intake of at least 1300 mg calcium each day along with 600 IU vitamin D,¹¹⁶ to participate in weight-bearing exercise regularly, and to stop smoking as important measures to promote skeletal health. Clinicians must remind patients that, as with all hormonal methods of contraception, condoms should be used in conjunction with DMPA for protection from STIs.

Combined Oral Contraceptive Pills

COCs have been available for more than 50 years. They are a reliable, effective method for the prevention of pregnancy, are available only by prescription in the United States, and are the most popular method of hormonal contraception among adolescents (see Tables 1 and 2). They are the prototype for other combined methods of birth control, including the vaginal ring and transdermal patch (discussed later), which have similar effectiveness, contraindications, medical benefits, and side-effect profiles.

COC Prescribing

COCs all contain an estrogen and a progestin. In almost every pill, the estrogen component is ethinyl estradiol, in amounts varying from 10 to 50 µg, with “low-dose” pills (35 µg or less) being first-line options for adolescents. An internal pelvic examination is not needed before initiation of this method nor any other method except an IUD. However, routine screening for STIs is recommended in all sexually active patients. (For a more complete discussion of gynecologic examinations of adolescents in the pediatric office

setting, see the 2010 AAP clinical report on the subject.¹¹⁷) COCs can be started on the same day as the visit (“quick start”), or on the day following EC use (see section on EC) in healthy, non-pregnant adolescents. Patients should be counseled that a back-up method (ie, condoms or abstinence) should be used for at least the first 7 days for contraceptive efficacy, and a condom should be used at all times for protection against STIs. A routine follow-up visit 1 to 3 months after initiating COCs is useful for addressing persistent adverse effects or adherence issues.

There is no 1 pill formulation that is the best choice for every adolescent, and even within the “low-dose” range, changing the amount of estrogen or the type of progestin may be necessary to address adverse effects or optimize medical benefits. Patients also should be informed of common transient adverse effects, including irregular bleeding, headache, and nausea. Neither weight gain nor mood changes have been reliably linked to use of combined hormonal contraception.^{118–120} Recommendations for managing adverse effects have been published elsewhere¹²¹ or can be found online (<http://www.managingcontraception.com/qa/index.php>). COCs have few contraindications in healthy female adolescents. They should not be prescribed for patients with severe and uncontrolled hypertension (systolic pressure ≥ 160 mm Hg or diastolic pressure ≥ 100 mm Hg); ongoing hepatic dysfunction; complicated valvular heart disease; migraines with aura or focal neurologic symptoms; complications of diabetes (ie, nephropathy, retinopathy, neuropathy, or other vascular disease); complicated solid organ transplantation; or thromboembolism or thrombophilia (eg, factor V Leiden mutation; antiphospholipid antibody syndrome; or protein C, protein S, or antithrombin 3 deficiency).¹¹¹ An excellent and up-to-

date resource for prescribing hormonal contraceptives, the “US Medical Eligibility Criteria for Contraceptive Use,” is available on the CDC Web site (<http://www.cdc.gov/reproductive-health/UnintendedPregnancy/USMEC.htm>) and in print.⁵⁸ These recommendations weigh the risks and benefits of contraceptive methods against unwanted pregnancy. When hormonal methods are used for medical therapy, the risk/benefit ratio may differ, and treatment decisions should be considered on a case-by-case basis. Other useful resources include a 2004 detailed discussion of contraceptive choices for patients with congenital heart disease¹²² and a recent publication offering expert guidance on prescribing contraception to adolescents at increased risk of hypercoagulability.¹²³ The most serious adverse event associated with COC use is the increased risk of blood clot, which is discussed in further detail in the following paragraphs.¹²⁴ Although smoking should be discouraged, it is not a contraindication to COC use in teenagers and young adults.⁵⁸

New data have continued to emerge regarding the risks and benefits of different progestins. On April 10, 2012, the FDA posted a drug safety communication that resulted in revised drug labels for COCs containing the progestin drospirenone.¹²⁵ These note that epidemiologic studies reported as high as a threefold increase in the risk of blood clots for drospirenone-containing products when compared with products containing levonorgestrel or some other progestins, whereas other epidemiologic studies found no additional risk of blood clots with drospirenone-containing products.

However, it is important to remember that most of the risk of blood clot is conferred from the estrogen component of the pill and that all COCs confer a lower risk of blood clot than

pregnancy.¹²⁶ The baseline incidence of venous thromboembolism in adolescents is up to 1 per 10 000 woman-years per year.¹²⁷ Currently available COCs increase the risk of blood clot three- to fourfold, or up to 4 per 10 000^{123,124} woman-years. In comparison, the incidence of venous thromboembolism (VTE) associated with pregnancy and the postpartum period is 10 to 20 per 10 000 woman-years, of which 1% to 2% are fatal.^{128,129}

COCs decrease the effectiveness of some medications (eg, lamotrigine). Conversely, other medications, such as anticonvulsants and antiretroviral agents, decrease COC effectiveness to the extent patients may need to choose alternative methods¹³⁰ (see Table 5 and Special Populations). With regard to antibiotics, neither a 2001 review of the literature¹³¹ nor a 2011 case-crossover study of 1330 COC failures¹³² found any definitive evidence of decreased COC effectiveness with the use of any antibiotic except rifampin.

Used perfectly, COCs are extremely effective, with a perfect-use failure rate for all users of 0.3%; however, the typical-use failure rate is 9%, suggesting that adherence is a key issue in COC use (see Table 4).⁴³ Counseling should include strategies to promote adherence, such as cell phone alarms and support from a family member or partner. Patients should be instructed on what to do if pills are missed. A missed pill should be taken as soon as it is remembered. If more than 1 pill in a row is missed, only the most recently missed pill should be taken as soon as possible, and the remaining pills should be taken at the usual time, reminding patients that 7 consecutive hormone pills are required to prevent ovulation. Further instructions can be accessed online at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w#Fig2.⁴² Patients should also be advised that EC

may be needed if 2 or more pills are missed in the first week or if 1 or more pills were missed earlier in the same cycle or late in the previous cycle (see online instructions and Fig 1 for details).

COC Regimens

COCs are currently available in fixed-dose, monophasic regimens (each tablet contains the same dose of estrogen and progestin) or in phasic regimens (triphasic and biphasic packs that contain varying doses of estrogen and progestin). Standard pill packs include 28 pills total, with 21 to 24 hormone pills and 4 to 7 placebo (hormone-free) pills. Among low-dose pills, there are no clear data suggesting one formulation is superior to another for adolescent use, so it is appropriate to choose one with the lowest copay on a patient's insurance formulary (if applicable). Many experts recommend starting adolescents on a monophasic pill with monthly bleeding and then changing regimens and/or extending cycles, as indicated, to address patient adverse effects or preference.¹²¹ Many adolescent medicine providers begin with a COC containing 30 to 35 µg of ethinyl estradiol and a progestin, such as levonorgestrel or norgestimate.

The benefits of decreasing or eliminating the placebo hormone-free interval (see section on COC benefits) have been increasingly recognized, and there are several regimens packaged with more than 21 active pills and fewer placebo pills. For example, some regimens (eg, Yaz [Bayer, Leverkusen, Germany], and Generess FE [Watson, Parsippany, NJ]) have 24 active pills and 4 pills without hormones. Several brands are available with 84 active pills and 7 placebos, or 84 active pills and 7 pills of low-dose estrogen (eg, Seasonique and LoSeasonique; Teva, Petah Tikva, Israel). In 2007, the FDA approved the first COC packaged with a year of continuous combined hormone pills, Lybrel (Pfizer, New York, NY).

COC Benefits

The noncontraceptive benefits of COC use include decreased menstrual cramping and blood loss and improvement in acne. Extended or continuous cycles may be particularly appropriate for adolescents with medical conditions, such as anemia, severe dysmenorrhea, endometriosis, abnormal uterine bleeding, and Von Willebrand and other bleeding diatheses and for adolescents who prefer amenorrhea.¹³³ These regimens may also be useful for conditions that are known to be exacerbated cyclically, such as migraine (without aura), epilepsy, irritable bowel syndrome, some psychiatric symptoms,¹³⁴ and behavioral problems (such as increased aggression or self-mutilation) that sometimes worsen cyclically in young women with profound cognitive impairment.¹³⁵ The most common adverse effect of extended-cycle regimens is unscheduled bleeding. Eliminating the hormone-free interval will also minimize fluctuations in medications that interact with COCs (see section on Special Populations). In addition, ovarian suppression is optimized by COC regimens with shorter or no placebo (hormone-free) intervals, potentially increasing contraceptive effectiveness, especially among adolescents who frequently miss pills.^{136–138}

Families can be reassured that COC use has not been shown to increase the risk of breast cancer.¹³⁹ Also, use of COCs for more than 3 years provides significant protection against endometrial and ovarian cancers.¹⁴⁰ Overall, COCs are one of the best-studied medications ever prescribed. Completely reversible and with no negative effect on long-term fertility, COCs are a safe option throughout a woman's reproductive years.

Contraceptive Vaginal Ring

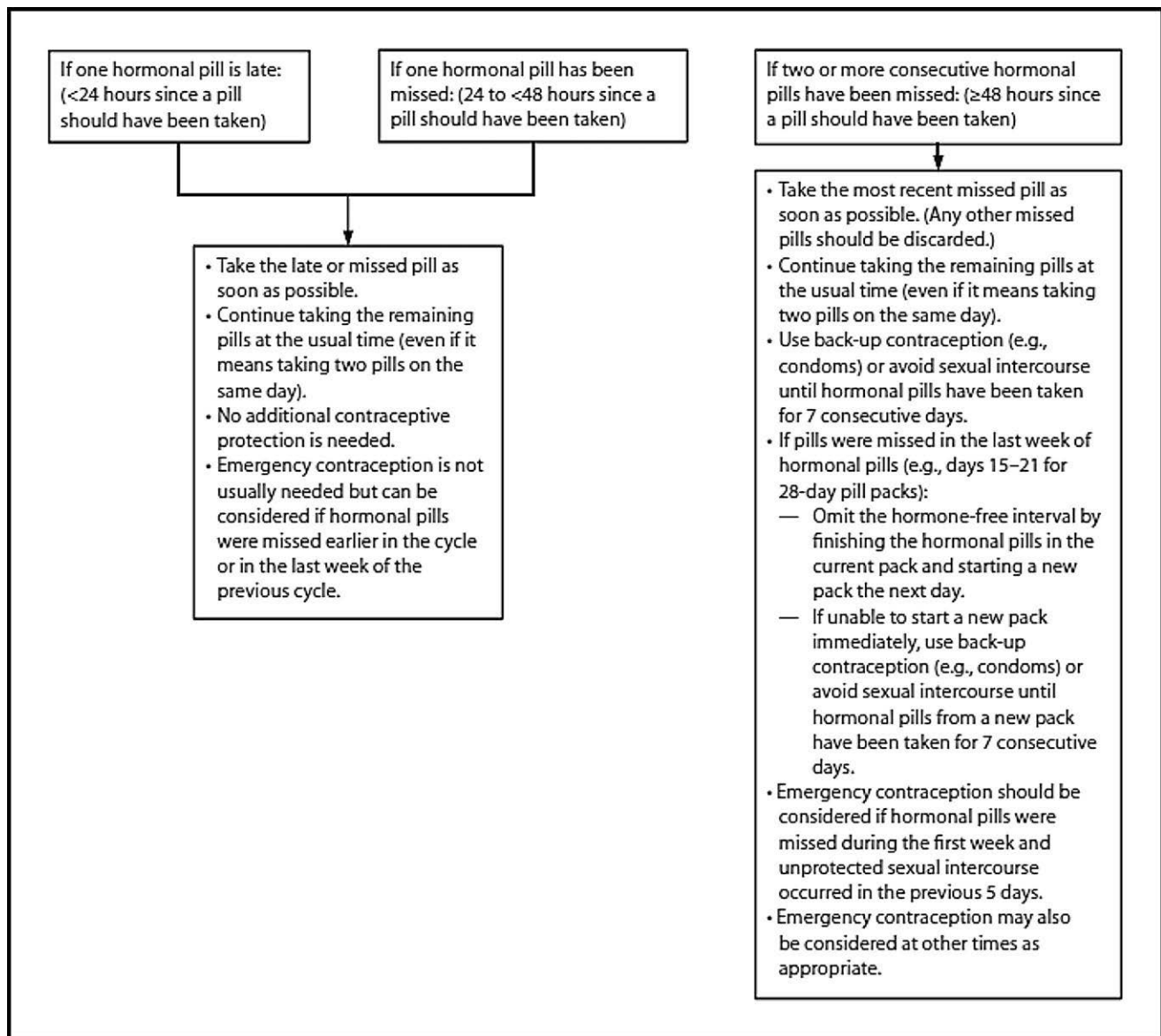
The vaginal ring (NuvaRing; Merck) releases 15 µg ethinyl estradiol and 120 µg etonogestrel (the active metabolite

of desogestrel) daily. It is a round, flexible device that measures 54 mm in outer diameter and 4 mm cross-sectionally. This soft silicone vaginal ring releases both estrogen and progestin hormones that protect against pregnancy for 1 month. It is inserted in the vagina and stays in place for 3 weeks, with removal for 1 week to induce menstruation followed by insertion of a new ring. Patients should be instructed to insert a new ring after 7 days even if bleeding has not ceased.

Because adolescents may be unfamiliar with their own reproductive anatomy, a pelvic model¹⁴¹ or other visual aid may be useful in explaining to patients where the ring will be. Patients should be reassured that the ring will not fall out. Eighty women (~90% of them nulliparous) were examined with the ring in place and none were able to expel the ring by bearing down in a Valsalva maneuver.¹⁴² The ring typically sits with the superior-most portion of the ring lying posterior to the cervix.¹⁴³

Most patients will not have previous experience with intravaginal medication and may have questions about its use, such as whether tampons can be worn when the ring is in place. On the basis of evaluation of serum concentrations of ethinyl estradiol and etonogestrel, contraceptive efficacy should not be compromised by concomitant use of tampons,¹⁴⁴ the spermicide nonoxonyl-9,¹⁴⁵ or intravaginal miconazole.¹⁴⁶ Similarly, the ring is intended to stay in place during coitus but can be removed for up to 3 hours if desired. This is not typically recommended, and sexually active patients may be reassured to know that most men were not bothered by its presence, if it was noted at all.^{142,147}

The ring has comparable typical-use failure rate (9%), risks, and benefits as other combined hormonal methods⁴³ but provides the simplest regimen.^{148,149} As with COCs, a same-day

**FIGURE 1**

Instructions for late and missed combined oral contraceptive pills.

start can be used with the vaginal ring. Adverse effects are largely similar to other combined methods, including breast tenderness, headaches, nausea, and breakthrough bleeding or spotting, with the additional vaginal symptoms of discharge, discomfort, and problems related to the device (eg, expulsion).¹⁵⁰ The limited investigation of bone health with the ring points to its bone neutrality, but these studies have not included adolescents younger than 18 years.^{151,152} Studies to date

have yielded inconsistent results about how the risk of VTE with use of the ring compares with the risk with use of low-dose COCs.^{153–156}

Analogous to experience with the contraceptive patch, it has not been clearly demonstrated that the simplified regimen afforded by the ring results in improved medication adherence or continuation in young people.¹⁵⁷ A trial of 237 college students randomized to use either the ring or COC found that perfect use was greater for the ring in

the first 2 months but that this was no longer statistically significant in the third month of the study. Similarly, 6-month continuation rates were no different and were less than 30% for both groups.¹⁵⁸

The ring is an excellent method for extended use. The vaginal ring package insert states that 1 ring can be used for up to 28 days with no back-up method; however, the rings contain sufficient medication to be used for up to 35 days¹⁵⁹ and, thus, can be replaced

once every calendar month. This eliminates the need for additional refills potentially not covered by insurers, which sometimes poses barriers to continuous pill and patch regimens. As with COCs, the longer the duration of continuous hormones, the greater the number of unscheduled bleeding days; however, the difference between a 28-day and 49-day cycle is small.¹⁶⁰ Similar to COCs, the decision about how often to allow uterine bleeding to occur can be individualized to the adolescent's medical needs and preferences. Women who choose to use the ring continuously with no planned ring-free days can be advised to remove the ring for 4 days if they have more than 5 days of consecutive bleeding, as this has been found to result in fewer bleeding days overall.¹⁶¹

Transdermal Contraceptive Patch

The combination hormone transdermal contraceptive patch (Ortho Evra [Ortho-McNeil Pharmaceutical, Raritan, NJ]) contains 0.6 mg norelgestromin and 0.75 mg ethinyl estradiol and measures approximately 1.75 × 1.75 in. The patch can be placed on the abdomen, upper torso, upper outer arm, or buttocks, using 1 patch for each of 3 weeks in a row, followed by 1 week off the patch, during which a withdrawal bleed usually occurs. Current estimates of failure rates for typical use are 9% (<1% for perfect use).⁴³ Approved by the FDA in November 2001, patch use rose in popularity until 2005, when use declined¹⁶² after publicity about increased estrogen exposure from the patch, which has been found to be 1.6 times higher than estrogen exposure with a COC.¹⁵³ The patch has undergone multiple label revisions, most recently August 22, 2012. The 2012 package insert contains a black box warning citing 5 US studies^{163–170} (1 with statistically significant findings) that suggest a possible increased risk of VTE compared with a 20- to 35-μg COC, with odds ratios

of 1.2 to 2.2. Although these potential health risks are concerning to some adolescents, the patch remains an important contraceptive alternative that may be the best option for some adolescents, especially in comparison with the many adverse consequences of unplanned pregnancy, which include an increased risk of VTE. Nonetheless, other methods may be safer first-line choices for patients interested in extended cycling.

The patch has comparable efficacy, benefits, and drug interactions as other combined methods, but provides a simpler regimen. Thus, it was initially assumed that the patch would promote improved contraceptive adherence in adolescents. Accordingly, early studies demonstrated better adherence to the patch than to COCs among adults,^{171,172} most notably among 18- and 19-year-olds,^{173,174} and 2 smaller studies of adolescents had high rates of self-reported short-term perfect patch use, 87% and 93%.^{175,176} However, contraceptive effectiveness requires that the method be sufficiently well accepted to be continued over time.

To our knowledge, there are no studies that have randomized adolescents to use either the patch or pills, and the observational studies that have compared these methods are plagued by possible selection bias; adolescents who choose a nondaily method may have behavioral characteristics that would interfere with continuation and perfect use of any method.^{177–179} For example, Bakhru and Stanwood¹⁷⁷ prospectively followed 1230 women (416 of whom were 17 years or younger) who self-selected their method and found 57% continuation of the patch at 1 year compared with 76% continuation of the pill ($P = .004$). In contrast to their initial hypothesis, patch users were significantly less likely than pill users to continue their method and, thus, were more likely to experience pregnancy.¹⁷⁷

Even lower rates of patch continuation, ranging from 25% to 50%, have been found in other longitudinal studies of adolescent patch users.^{179–181}

In addition, similar findings have been shown in randomized studies of adults. A 2010 Cochrane review¹⁸² (based on 4 such studies) concluded that patch users were more likely than pill users to discontinue study participation because of adverse effects. Similarly, in a study that randomized 500 women (average age, 25–26 years) to either the patch or the contraceptive vaginal ring, only 27% of patch users (versus 71% of ring users) planned to continue their assigned method after the 3-month study concluded.¹⁸³

Side effects of the patch are largely similar to other combined methods, with the addition of local adverse effects, such as dislodged patches and hyperpigmentation,^{175,176} contact dermatitis and other skin irritation,¹⁸⁴ and concerns about the visibility and appearance of the patch.^{185,186} Investigations into the patch's effect on bone health have yielded inconsistent results, with findings in adults^{150,151} more reassuring than those in adolescents.¹⁸⁷ However, this limited work is far from conclusive.

Progestin-Only Pills

Progestin-only pills (POPs, also known as “mini-pills”) work primarily by thickening cervical mucus, not by inhibiting ovulation. Because of the timing of this effect, it is generally recommended that pills be taken between 4 and 22 hours before coitus usually takes place. Perfect and typical-use failure rates for POPs are not calculated separately from those of combined hormonal contraceptives. Given the importance of even small variations in the timing of pill administration and the continued potential for ovulation, POPs are generally held to be less effective than combined hormonal methods.

Similar to other progestin-only methods, irregular bleeding is a common adverse effect. However, POPs are markedly less effective than other progestin-only methods, including the progestin-containing IUD, the progestin implant, and injectable progestin. Therefore, POPs are not typically recommended as a first-choice contraceptive in healthy adolescents. Nonetheless, they provide a progestin-only alternative for selected adolescent patients with demonstrated excellent medication adherence.

Male Condoms

The male condom is a mechanical barrier method of contraception and STI prevention. In a recent nationally representative survey, condom use was reported at first intercourse by 68% of adolescent girls and 80% of adolescent boys and at most recent intercourse by 52% of adolescent girls and 75% of adolescent boys.¹⁸⁸ Male condoms have several advantages for adolescents, including involving males in the responsibility of contraception, easy accessibility and availability to minors, use without a prescription, and low-cost STI protection.

Male condoms are most commonly made of latex. Lubricated condoms are used for vaginal and anal intercourse; unlubricated condoms are available for oral sex. Although many individuals will need additional lubrication with condoms, adolescents' lubricant use is rarely assessed. Condoms should be used only with water-based lubricants (eg, K-Y Jelly [McNeil PPC Inc, Fort Washington, PA], Astroglide [Biofilm Inc, Vista, CA]), because oil-based lubricants (eg, petroleum jelly, massage oils, body lotions) can weaken latex and cause breakage. Male condoms also are available as polyurethane (synthetic) for people with latex sensitivities and as natural membrane (eg, lamb cecum). Polyurethane condoms have similar effectiveness to latex condoms

but are more resistant to deterioration and are compatible with both oil- and water-based lubricants. Natural membrane condoms are porous and provide inadequate STI protection.

Condom effectiveness depends on consistent and correct use (see Table 6).¹⁸⁹ For pregnancy prevention, the failure rate at the end of first-year use for the male latex condom is 2% with perfect use and 18% with typical use.^{43,190} Consistent evidence supports condoms as reducing the risk of disease transmitted to and from the penile urethra, including gonorrhea, *Chlamydia*, trichomoniasis, hepatitis B, and HIV.^{191–195} Emerging evidence also supports condoms as reducing the risk of acquiring diseases transmitted through skin or mucosal contact, including genital herpes simplex virus,^{196,197} human papillomavirus,^{198,199} and syphilis.²⁰⁰ Because condoms protect against STIs, all sexually active adolescents should be encouraged to use condoms, regardless of whether an additional contraceptive method is used. Instructions for condom use can be found in Table 6. Additional details on condoms and recommendations can be found in the AAP policy statement on condom use by adolescents.²⁰¹ Despite increases in condom use, many adolescents do not use condoms effectively or at all. Condom use is influenced by individual, relationship, and broader social and structural factors,^{202–204} which should be addressed on multiple levels, including provider counseling, sex education, and interventions to improve access. Because condom use requires cooperation and communication between partners, condom use within relationships changes as relationships evolve²⁰⁵ and commonly declines in established relationships.^{206,207}

Emergency Contraception

In the United States, the available methods of EC include orally administered hormones, either in a progestin-

only dedicated EC product (levonorgestrel, 1.5 mg) or in high-dose combined estrogen and progestin oral contraceptive pills (the Yuzpe regimen); ulipristal acetate (a progesterone receptor modulator); and insertion of a copper IUD. These methods can prevent pregnancy when initiated up to 5 days after an act of underprotected sexual intercourse but are more effective the sooner they are used. Data suggest that ulipristal acetate, approved by the FDA in 2010, may have increased effectiveness over oral levonorgestrel at the end of the 5-day window of use and in heavier women.^{208–210} On the basis of data demonstrating that the levonorgestrel EC pill loses effectiveness in women who weigh more than 165 pounds and is ineffective in women who weigh more than 176 pounds, the levonorgestrel EC pill is undergoing revised labeling in Europe, and the FDA is considering whether to require similar revisions in the United States.²¹¹

Unlike ulipristal, which is pregnancy category X, levonorgestrel does not have teratogenic or other adverse effects on the fetus,²¹² and a pregnancy test is not necessary before prescribing levonorgestrel EC.²¹³ Levonorgestrel EC is estimated to be up to 85% effective.^{213,214} Additional details on prescribing EC can be found in the AAP policy statement on emergency contraception,²¹³ and additional guidance can be found at <http://ec.princeton.edu/questions/dose.html#dose>.

Plan B One-Step (Teva Pharmaceuticals, Petah Tikva, Israel), a dedicated progestin-only method, is approved by the FDA as a nonprescription product for all women of childbearing potential. Generic versions are approved as nonprescription for women 17 years of age and older; however, proof of age is not required to purchase them.

Given the barriers to EC access and the importance of timely use, advance prescription for EC should be a part of routine adolescent care.²¹³ There are

TABLE 6 How to Use a Condom Effectively

Before: Store condoms in a cool, dry place. Heat, including body heat from a pocket, can cause latex to degrade over time. Check the expiration date before use.

1. Use a new condom for every act of vaginal, anal, and oral sex throughout the entire sex act (from start to finish).
2. Before any genital contact, put the condom on the tip of the erect penis with the rolled side out.
3. If the condom does not have a reservoir tip, pinch the tip enough to leave a half-inch space for semen to collect. Holding the tip, unroll the condom all the way to the base of the erect penis.
4. After ejaculation and before the penis gets soft, grip the rim of the condom and carefully withdraw. Then gently pull the condom off the penis, making sure that semen does not spill out.
5. Wrap the condom in a tissue and throw it in the trash where others will not handle it.
6. If you feel the condom break at any point during sexual activity, stop immediately, withdraw, remove the broken condom, and put on a new condom.
7. Ensure that adequate lubrication is used during vaginal and anal sex, which might require water-based lubricants. Oil-based lubricants (eg, petroleum jelly, shortening, mineral oil, massage oils, body lotions, and cooking oil) should not be used, because they can weaken latex, causing breakage.

no medical contraindications to this method, and multiple studies have found that providing EC in advance increases the likelihood of women using it when it is needed and does not increase sexual or contraceptive risk-taking behavior.^{215,216} Given the sometimes sporadic and unplanned nature of adolescent sexual behavior, counseling and advance provision of EC should be a part of anticipatory guidance.

Other Barrier Methods

Female Condoms

The female condom is a polyurethane or synthetic nitrile pouch with 2 flexible rings, one fitting inside the vagina and the other on the perineum. Female condoms have a perfect-use failure rate of 5% and a typical-use failure rate of 21%.⁴³ Among US adolescents and young adults, the female condom

has had very low uptake,²¹⁷ in part because of higher cost, less availability, lack of knowledge, and negative attitudes toward female condoms.

Vaginal Spermicides

Vaginal spermicides are a chemical barrier method (most commonly nonoxynol-9) applied intravaginally through a variety of forms: gel, foam, suppository, or film. Spermicides consist of 2 components: a formulation (the gel, foam, suppository, or film) and the chemical ingredient that kills the sperm. Table 4 describes typical- and perfect-use failure rates for vaginal spermicides. The CDC identifies being at high risk for HIV (eg, commercial sex workers) and HIV infection as contraindications for use of spermicides, as use can disrupt the cervical mucosa, potentially increasing risk of HIV acquisition or increased viral shedding and transmission of HIV.^{58,218}

Diaphragm, Cervical Cap, and Contraceptive Sponge

The diaphragm, cervical cap, and sponge are barrier methods of contraception. They are less commonly recommended for adolescents, because they do not provide STI protection and have lower effectiveness rates than other methods.⁴³ Diaphragms are flexible latex cups used with spermicide that are inserted into the vagina before intercourse and must remain in place for 6 hours after intercourse. Cervical caps are latex or silicone cups with a firm rim that adhere to the cervix and provide continuous contraceptive protection for up to 48 hours. Sponges are polyurethane sponges that contain nonoxynol-9 spermicide. They are approximately 2 inches in diameter, can be inserted up to 24 hours in advance, and must be left in place for 6 hours after intercourse. Sponges are available over the counter. Diaphragms and caps require fitting by a health care pro-

fessional. Table 4 provides typical- and perfect-use failure rates for the diaphragm, cervical cap, and contraceptive sponge. For the sponge, typical- and perfect-use failure rates are as much as 16% and 11%, respectively.²¹⁹ These methods are contraindicated in women at high risk of HIV or women with HIV infection, because the concomitant spermicide use may increase risk of HIV acquisition or transmission.⁵⁸ Detailed information can be found in *Contraceptive Technology*.⁴¹

Fertility Awareness and Other Periodic Abstinence Methods

Periodic abstinence methods identify fertile days within each menstrual cycle, and the individual abstains during those fertile times. Fertile days can be determined using a menstrual calendar, basal body temperature, and cervical mucus consistency. In a recent national survey, 17% of adolescents report ever using periodic abstinence.⁶ Among both adults and adolescents, as many as 24% of individuals reporting periodic abstinence as their primary method of contraception will experience an unintended pregnancy within the first year of use. More concerning is the poor continuation rates for the method,²²⁰ even for individuals participating in clinical trials.²²¹ An additional challenge with adolescents is that ovulation may not be predictable in the first few year(s) after menarche. If periodic abstinence is used, counseling on dual use of a condom and more reliable alternative methods should be offered. More detailed information can be found in *Contraceptive Technology*.⁴¹

Withdrawal

Withdrawal, or coitus interruptus, is a method in which the male partner attempts to “pull out” his penis before ejaculation. Although typically considered a “nonmethod,” withdrawal is commonly practiced by both adults

and adolescents. In the National Survey of Family Growth 2006 to 2008, 8% to 11% of respondents reported using withdrawal at first sex,⁶ and in the 2006 to 2010 survey, 57% of adolescents reported ever using withdrawal as a contraceptive method.¹⁸⁸ Adolescents' reasons for using withdrawal include dissatisfaction with hormonal methods, and as a secondary or backup method to condoms or hormonal contraception.²²² Relationship development and the establishment of trust also were cited as reasons for use of withdrawal.²²² The typical-use failure rate of withdrawal across all age groups is 22%⁴³; however, unlike condoms, it provides no STI protection. Because of the common use of withdrawal, pediatricians should remember to ask about it; because of the limited effectiveness⁴³ and lack of STI protection afforded by withdrawal, pediatricians should encourage adolescents to adopt more effective hormonal and/or barrier methods.

SPECIAL POPULATIONS

Pediatricians care for adolescents with a range of medical conditions that can affect sexuality, sexual behavior, and contraceptive needs. The CDC has recently addressed the contraceptive needs of young women with medical conditions in its publication "US Medical Eligibility Criteria for Contraceptive Use."⁵⁸ Available online, this document summarizes the literature on safety and efficacy of different contraceptive methods by medical condition. Populations of particular importance to pediatricians are summarized as follows.

Adolescents With Disabilities

An estimated 16% to 25% of adolescents are identified as having special health care needs, including physical disability, developmental disability, and chronic illness.²²³ Sexuality and sexual health care needs in this population are often overlooked, yet data reveal

that adolescents with disabilities and chronic illnesses have similar levels of sexual behaviors and sexual health outcomes (eg, STIs).^{224,225} Adolescents with disabilities and chronic illnesses also have similar needs for counseling and support of healthy sexuality development.^{226,227} These data underscore the need for pediatricians to address sexuality and contraception as part of routine care and as a core function of a medical home, particularly for adolescents using teratogenic medications.

Adolescents with more severe physical disabilities or cognitive impairment may need hormonal contraceptives for menstrual control and hygiene. Adolescents with disabilities may have early or irregular menstrual cycles,²²⁸ and medications such as certain anticonvulsants and antipsychotics may influence the neuroendocrine system, leading to abnormal bleeding.²²⁹ Menstrual hygiene also may present a special problem for adolescents with motility and transfer difficulties, as well as for those with behavioral and developmental disabilities.²³⁰ Menstrual control and suppression is commonly achieved with COCs, transdermal patches, DMPA, and levonorgestrel IUDs.^{77,231,232} Continuous or extended cycles of COCs is a common approach,^{231,232} and there are reports of successful use of 52-mg levonorgestrel IUDs in adolescent patients.^{76,77,80} Surgical approaches (tubal ligation, endometrial ablation, or hysterectomy) are rarely necessary and present special ethical and legal issues. A detailed discussion of menstrual management for adolescents with disabilities can be found in recent review articles as well as professional consensus statements.^{231–233}

Adolescents With Obesity

Similar to adolescents with disabilities, sexuality and sexual health are often overlooked among adolescents with obesity. Although national

data demonstrate some weight and BMI-related variation in body image and sexual behaviors, the sexual behaviors and sexual health needs of adolescents with obesity are substantially similar to those of their normal-weight peers.^{234,235} Obesity and related endocrine effects may influence the efficacy and adverse effect profiles of contraceptives, including EC (see previous section on EC). Excess pregnancies were found among transdermal contraceptive patch users weighing more than 90 kg (198 lb; 0.9% vs 0.3% among "perfect" users).^{236,237} Data are limited and inconsistent about whether hormonal contraceptive effectiveness varies by body weight or BMI.⁵⁸ Systematic reviews and large cohort studies have revealed no or mixed effects for the effect of both body weight and BMI on COCs, IUDs, implants, and contraceptive injections.^{238–240} When examining complications, the World Health Organization and CDC found that among adult women, COC users with obesity are more likely than nonusers to experience thromboembolic complications.¹¹¹ However, the absolute risk of thromboembolic complications among adolescent COC users is low.

Women with obesity, either with or without polycystic ovary syndrome, are often anovulatory and experience infrequent menses. Metformin is frequently used in the treatment of these women and can increase the frequency of ovulation, increasing their contraceptive needs. A frequent concern by both adolescents and providers is additional weight gain with hormonal contraceptive use among adolescents with obesity. Adult data suggest that women with obesity are not more likely to have significant weight gain with combined or progestin-only contraceptives.^{241–243} In contrast, adolescents with obesity who used DMPA were more likely than normal-weight nonusers,

COC users with obesity, and normal-weight DMPA users to gain weight.⁹⁶

Increasing numbers of adolescents are having bariatric surgery performed, and these patients present special contraceptive needs. Presurgery data reveal a high prevalence of menstrual problems among adolescents with morbid obesity.⁸¹ Postsurgery data demonstrate an improvement in fertility, and professional consensus statements recommend delaying pregnancy for at least 12 to 18 months after bariatric surgery.²⁴⁴ Together, these suggest a need for highly effective contraceptives in such patients. The surgical procedures themselves may influence effectiveness of contraceptives. Postoperative complications, such as long-term diarrhea and/or vomiting, have the potential to decrease COC effectiveness.⁵⁸ Additionally, surgical procedures involving a malabsorptive component have the potential to decrease COC effectiveness.⁵⁸ Similar concerns about decreased COC effectiveness have not been described with laparoscopic placement of an adjustable gastric band. Given the challenges with oral, transdermal, and injectable contraceptives and the need for effective long-term postprocedure contraceptives, there is increasing use and success with levonorgestrel IUDs placed at the time of surgery.⁸¹

Adolescents With HIV

The vast majority of adolescents with HIV acquire their infection during adolescence through sex, intravenous drug use, or other behavioral mechanisms. Only a small proportion of adolescents with HIV are infected perinatally. National data reveal that sexual behaviors of HIV-infected adolescents do not differ substantially from their uninfected peers, and therefore, these adolescents have similar contraceptive and sexual health needs. However, because of risks of transmission to partners and because of drug interactions with antiretroviral

therapy (ART), adolescents with HIV infection present a challenge to prescribing contraception. Many antiretroviral agents have interactions with COCs, and a physician with expertise in HIV care should be consulted when prescribing hormonal contraception for an HIV-infected adolescent on ART.^{58,245} The CDC and the World Health Organization provide guidance on prescribing different contraceptives for patients with HIV infection receiving ART.²⁴⁶ Condoms are the preferred method of barrier contraception because of their demonstrated ability to decrease HIV transmission. Spermicides and diaphragms are contraindicated among HIV-positive women because of the potential for increased risk of genital lesions and potential increased risk of HIV transmission associated with nonoxynol-9. IUDs do not increase the risk of HIV acquisition or transmission and are safe and effective for HIV-infected individuals without increasing the risk of infections or complications in HIV-infected women. If COCs are used in HIV-infected adolescents receiving ART, a preparation containing ethinyl estradiol $\geq 30 \mu\text{g}$ should be prescribed.⁵⁸

Data on the interactions between ART and hormonal contraceptives (both combined and progestin only) are limited, but effects are known to include increased ART toxicity and, in the case of ritonavir-boosted protease inhibitors, decreased contraceptive steroid concentrations, potentially compromising contraceptive effectiveness. Other ART regimens (eg, zidovudine-containing regimens) are teratogenic, necessitating highly effective contraceptives.²⁴⁶

Adolescent Recipients of Solid Organ Transplantation

The improved survival of pediatric recipients of solid organ transplantation has prompted increased attention to

quality-of-life issues, including involvement in romantic and sexual relationships, issues that are typically addressed by the patient's pediatrician. Neither transplantation nor immunosuppressant medications decrease fertility, and conception can occur as early as 3 weeks after liver transplantation.^{247,248} Similar to other adolescents with chronic illnesses, transplant recipients are likely to be as sexually active as their peers.^{225,249–253} However, because these patients may underestimate their own fertility and because subspecialty physicians underestimate sexual activity and contraceptive needs in patients with chronic disease, it is imperative that primary care physicians assess these issues.^{254–256}

For transplant recipients who choose not to remain abstinent, a highly effective method is indicated. Patients who have established normal organ function and are stable at least 6 to 8 months after transplantation can use any of the currently available hormonal contraceptives, provided they do not have other contraindications to the estrogen component.^{58,254,257,258–260} Contraindications to estrogen, however, occur more commonly in transplant recipients. For example, COCs should not be prescribed to patients with active liver dysfunction or coronary artery disease.¹³⁹ Also, deterioration of organ function or episodes of rejection would require reevaluation and consideration of substituting a nonhormonal method, at least temporarily. Given the excess risks associated with unplanned pregnancies in transplant recipients, knowledge about the availability of EC is especially important.

Potential drug interactions should be assessed, both to avoid drug toxicities and to maintain the effectiveness of all prescribed medications.²⁶¹ For example, COCs can increase concentrations of immunosuppressive medications, such as cyclosporine, which has a narrow

therapeutic window and significant toxicities (see Table 7). Patient care decisions may require consultation with a clinical pharmacologist. To avoid monthly fluctuations in drug concentrations, patients using combined methods should use them continuously, without a hormone-free interval. Although 1 study suggests that immunosuppressant concentrations remain stable with use of the contraceptive vaginal ring,²⁵⁹ both the ring and the patch are sufficiently similar to COCs that, until further data are available, they should be used with the same precautions that apply to COCs. Drug interactions with progestin-only methods are uncommon; however, monitoring cyclosporine concentrations is advisable.²⁶²

Historically, IUDs have been considered contraindicated in immunosuppressed patients because of theoretical risks of both decreased efficacy and increased risk of infection. However, more recent evidence argues against these

theoretical risks,²⁶³ and the CDC does not consider IUDs contraindicated in patients with stable graft function.⁵⁸ Although data are currently limited, anecdotal experience with adult transplant recipients suggests the levonorgestrel IUD can be an excellent choice because of the lack of drug interactions and outstanding contraceptive effectiveness.

Adolescent Oncology and Other Medically Complex Patients

Pediatricians may be called on to provide contraceptives for patients with cancer and other complex medical illnesses. In addition to pregnancy prevention, these adolescents may need menstrual suppression for heavy menstrual bleeding, bleeding disorders, or chemotherapy. Other medical conditions, such as rheumatologic illnesses, may present issues related to estrogen use, thromboembolism, or medication interactions. For these and other complex illnesses, the principles

have been discussed in the previous sections, and consultation with appropriate adolescent medicine, adolescent gynecology, or family-planning specialists can be sought.

ADHERENCE AND FOLLOW-UP

Frequent follow-up is important to maximize adherence for all methods of contraception, to promote and reinforce healthy decision-making, and to screen periodically for risk-taking behaviors and STIs. Follow-up visits should include routine examinations, reassessment for contraception method, STI surveillance, and other sexual health preventive measures, such as human papillomavirus immunization. The timing and frequency of reassessment will vary depending on the contraceptive method and the patient's other health needs. An internal pelvic examination is not necessary for hormonal contraception (for a more complete discussion of

TABLE 7 Immunosuppressant Adverse Effects and Interactions With Hormonal Contraception

Type of Medication	Drug Interactions	Adverse Effects Influencing Contraception	Contraceptive Considerations
Corticosteroids (prednisone)	COCs may increase plasma concentrations of corticosteroids; monitor for increased corticosteroid effects	Hypertension Diabetes Weight gain, osteoporosis	Severe and uncontrolled hypertension is a contraindication to COC use. Low-dose pills have minimal impact on glucose metabolism. Monitor weight and BMD carefully if DMPA is used.
Azathioprine (Imuran ^a)		Liver toxicity	Liver dysfunction interferes with estrogen metabolism.
Mycophenolate mofetil (CellCept ^b)		Diarrhea, vomiting	Severe gastrointestinal disturbance could decrease COC absorption.
Cyclosporine, tacrolimus (Prograf, ^c FK506)	COCs may increase levels; monitor blood levels closely	Hypertension Hyperlipidemia Hyperkalemia Diabetes Headache	Severe hypertension is a contraindication to COC use. COCs have minimal effect on lipids. Drospirenone (a progestin with spironolactone-like activity) is contraindicated with hyperkalemia. Low-dose pills have minimal impact on glucose metabolism. Headache can be an adverse effect of steroid hormones: monitor headache frequency. ^d
Sirolimus (Rapamune ^e)	COCs may increase levels; monitor blood levels closely	Hyperlipidemia	COCs have minimal effect on lipids.

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^a Triton Pharma Inc, Concord, Ontario.

^b Genentech USA Inc, South San Francisco, CA.

^c Astellas Ireland Co Ltd, Kerry, Ireland.

^d If headaches increase after initiation of contraceptive method or neurologic symptoms accompany migraine headache, consider changing method.

^e Pfizer, Philadelphia, PA.

gynecologic examinations of adolescents in the pediatric office setting, see the 2010 AAP clinical report on gynecologic examinations for adolescents).¹¹⁷ Regularly scheduled visits need to occur to assess contraceptive issues, such as use, adherence, adverse effects, and complications. Adolescents should receive ongoing support and reinforcement by using motivational interviewing approaches to enhance effective and consistent contraceptive use, including engaging parental support for contraceptive adherence, when possible. In addition, condom use at each sexual intercourse must be advised and reinforced at every visit. Individual factors, relationship factors, family support, knowledge and

understanding of contraceptives, personal resources, access to confidential care, and fertility intentions have all been demonstrated to affect adolescent contraceptive choice. Adolescents rely on trusted health professionals, such as pediatricians, for accurate information, for individualized counseling and prescribing, and for support and problem-solving around continuation and adherence.

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Death of a Child in the Emergency Department

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- *Policy Statement*

POLICY STATEMENT

Death of a Child in the Emergency Department

abstract

FREE

The American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association have collaborated to identify practices and principles to guide the care of children, families, and staff in the challenging and uncommon event of the death of a child in the emergency department in this policy statement and in an accompanying technical report. *Pediatrics* 2014;134:198–201

INTRODUCTION

The death of a child in the emergency department (ED) is an event with emotional, cultural, procedural, and legal challenges. The original policy statement, “Death of a Child in the Emergency Department: Joint Statement by the American Academy of Pediatrics and the American College of Emergency Physicians,” was first published in 2002.¹ It represented a groundbreaking collaboration between general and pediatric emergency practitioners regarding their professional obligations in managing the death of a child in the ED, recognized as one of the most difficult challenges in emergency care. This revised statement expands that collaboration to include emergency nursing and is issued jointly by the American Academy of Pediatrics (AAP), the American College of Emergency Physicians (ACEP), and the Emergency Nurses Association (ENA). The infrequency of child death in the ED and the enormity of the tragedy magnify the challenges in simultaneously providing clinical care, holistic support for families, and care of the team delivering care while attending to significant operational, legal, ethical, and spiritual issues. The evidence basis for these recommendations is detailed in the accompanying technical report of the same title.²

RECOMMENDATIONS

The AAP, ACEP, and ENA support the following principles:

- The ED health care team uses a patient-centered, family-focused, and team-oriented approach when a child dies in the ED.
- The ED health care team provides personal, compassionate, and individualized support to families while respecting social, spiritual, and cultural diversity.
- The ED health care team provides effective, timely, attentive, and sensitive palliative care to patients with life span-limiting conditions and anticipated death presenting to the ED for end-of-life care.
- The ED health care team clarifies with the family the child’s medical home and promptly notifies the child’s primary care provider and appropriate subspecialty providers of the death and, as appropriate,

AMERICAN ACADEMY OF PEDIATRICS Committee on Pediatric Emergency Medicine, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS Pediatric Emergency Medicine Committee, and EMERGENCY NURSES ASSOCIATION Pediatric Committee

KEY WORDS

emergency department, death, child, pediatrician, nurse

ABBREVIATIONS

AAP—American Academy of Pediatrics

ACEP—American College of Emergency Physicians

ED—emergency department

ENA—Emergency Nurses Association

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The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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coordinates with the medical home and primary care provider in follow-up of any postmortem examination.

- ED procedures provide a coordinated response to a child's death including the following:
 - Written protocols regarding
 - family member presence during and after attempted resuscitation;
 - preterm delivery resuscitation;
 - end-of-life care/anticipated death in the ED of a child with a life span-limiting condition;
 - collaboration with law enforcement staff to address forensic concerns while providing compassionate care;
 - institutional position on permitting the practice of procedures involving the newly deceased; and
 - best practice—outlining procedures after the death of a child (eg, a “death packet” with guidelines for completion of a death certificate, organ donation, etc)
 - Processes for notification of primary care and subspecialty providers and medical home of the impending death or death of their patient
 - Identification of resources, including other individuals and organizations, that can respond to the ED to assist staff and bereaved families, such as child life, chaplaincy, social work, behavioral health, hospice, or palliative care staff
 - Identification and notification of medical examiner/coroner regarding all deaths, as directed by applicable law
 - Routine offering of postmortem autopsy to families for all non-medical examiner-coroner cases
 - Clear processes for organ and tissue procurement
 - Identification and reporting of cases of suspected child maltreatment
 - Formal voluntary support and programs for ED staff and trainees, out-of-hospital providers, and others who are experiencing distress
 - Support of child death review activities to understand causes of preventable child death
- Emergency medicine, pediatric resident, and emergency nurse training includes specific education regarding the difficult issues raised by the death of a child in the ED, such as the following:
 - Evidence for supporting family presence during attempted resuscitation
 - Best palliative care practices for imminently dying pediatric patients
 - Communicating the news of the death of a child in the ED to parents and family
 - Best practice in discussion of organ donation or autopsy
 - Filing the report of suspected child abuse or neglect in the setting of a child death
 - Medical-legal issues and best practice surrounding completion of death certificates
 - Optimal documentation and collaboration with state and local child death review teams to identify strategies to prevent future child deaths
 - Self-care after difficult or troubling ED cases
- The ED health care team routinely considers care for the bereaved members of the patient's family that may include information and arrangements for bereavement care services, condolence cards,

and follow-up with family to address any concerns or questions.

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Death of a Child in the Emergency Department

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- *Technical Report*

TECHNICAL REPORT

Death of a Child in the Emergency Department

Patricia O'Malley, MD, Isabel Barata, MD, Sally Snow, RN, AMERICAN ACADEMY OF PEDIATRICS Committee on Pediatric Emergency Medicine, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS Pediatric Emergency Medicine Committee, and EMERGENCY NURSES ASSOCIATION Pediatric Committee

KEY WORDS

death of a child, emergency department

ABBREVIATIONS

AAP—American Academy of Pediatrics
ACEP—American College of Emergency Physicians
ED—emergency department
EMS—emergency medical services
ENA—Emergency Nurses Association
CFRT—child fatality review team
CPR—cardiopulmonary resuscitation
OPO—organ procurement organization
NRP—Neonatal Resuscitation Program

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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The death of a child in the emergency department (ED) is one of the most challenging problems facing ED clinicians. This revised technical report and accompanying policy statement reaffirm principles of patient- and family-centered care. Recent literature is examined regarding family presence, termination of resuscitation, bereavement responsibilities of ED clinicians, support of child fatality review efforts, and other issues inherent in caring for the patient, family, and staff when a child dies in the ED. Appendices are provided that offer an approach to bereavement activities in the ED, carrying out forensic responsibilities while providing compassionate care, communicating the news of the death of a child in the acute setting, providing a closing ritual at the time of terminating resuscitation efforts, and managing the child with a terminal condition who presents near death in the ED. *Pediatrics* 2014;134:e313–e330

INTRODUCTION

When emergency clinicians are faced with an imminent child death in the emergency department (ED), they must carry out many complex tasks. They must treat a patient experiencing an acute and evolving medical situation, establish a compassionate relationship with family they have likely never met before, and support and work in team fashion with their colleagues as they acknowledge the human limitations to remedy a medical crisis. Many of the clinical, operational, legal, ethical, and spiritual layers to this complex care are discussed in this report and are listed in Table 1. The infrequency of these events and the magnitude of the tragedy combine to make the death of a child in the ED one of the most challenging problems facing emergency health care providers.

Despite the relative infrequency of these events, there is considerable diversity in the clinical presentation of the death of a child in the ED. In this technical report, child death in the ED is considered broadly, encompassing acute unanticipated trauma or illness, stillbirth or extreme preterm birth at the margin of viability, the child declared dead on arrival, the child who dies shortly after passing through the ED, and even the child with a known life span-limiting condition for whom the ED becomes the location of end-of-life care.

This technical report builds on the original technical report published in *Pediatrics* in 2005¹ in support of the 2002 joint statement of the American Academy of Pediatrics (AAP) and American College of Emergency Physicians (ACEP)² and a companion article published in *Annals of*

TABLE 1 Essential Components of Care in the ED When a Child Dies

Clinical
Resuscitation best practice
Termination of resuscitation
Identifying, validating, and respecting advanced care directives
Operational
Staff training in communication
Team response (including readily available support staff such as security, child life, chaplaincy, social work)
Family presence policy
Dealing with media ^a
Communication with medical home
Defusing/debriefing for team
Private location for family to be with deceased, means and location to conduct rituals
Legal and forensic
Organ donation
Autopsy
Working with police and coroner/medical examiner
Child protective services
Child fatality review team
Documentation in medical record
Preservation of evidence
Ethical
Resuscitation: how long is too long?
Prolongation of resuscitation efforts for family presence/organ donation
Practice on newly deceased
Initiation of resuscitation at the border of viability in extreme preterm birth
Spiritual and emotional
Needs of family, including saying goodbye, memory making
Needs of multidisciplinary team
Envisioning a “good death” in the ED
Follow-up care for family
Helping family to know everything was done
Assisting family in explaining to siblings, family, friends
Assisting family in locating community support to address grief and bereavement
Plan for postautopsy meeting to answer questions
Plan for scheduled follow-ups and marking of meaningful dates
Follow-up care for team
Scheduled voluntary defusing/debriefing with all members of the emergency care team who wish to participate

^a Not covered in this report.

Emergency Medicine in 2003.³ These earlier publications called for a patient- and family-centered and team-oriented approach to the provision of compassionate care while respecting social, spiritual, and cultural diversity. They outlined responsibilities of the ED staff

involved in the care of the child, including the responsibility to facilitate organ procurement and obtain consent for postmortem examinations; to facilitate the identification of medical examiner cases and the reporting of potential maltreatment cases; to assist team members, including emergency medical services (EMS) personnel, with managing critical incident stress; to notify the primary care provider and other clinicians/specialists; and to delineate the responsibility of follow-up of autopsy reports or other medical information. This revised report, as well as the accompanying revised policy statement of the same title,⁴ reaffirms those principles and examines recent literature regarding family presence during attempted resuscitation, recommendations regarding termination of resuscitation efforts, organ donation, benefit of autopsy, practicing procedures on the newly deceased, benefit of continued contact with surviving family members, and working to support state, local, and national child fatality review teams. New observations regarding the need for and the most effective ways to provide communication training, reflections on the effect of patient death on providers, and definitions of a “good death” are also reviewed. Additional existing resources from the emergency care literature are identified. Observations from venues outside the ED but with potential application to the ED setting are considered. Finally, a reconsideration of what can be called success in pediatric resuscitation is offered.

BACKGROUND

Data from the National Center for Health Statistics for the most recent year completed (2009) revealed that there were 73 million children younger than 18 years residing in the United States.⁵ Although the portion of the population younger than 18 years is

roughly 30% of the total population, fewer than 2% (48 000) of deaths occur in this age range. This statistic is strikingly different from a century ago, when 30% of all deaths were in children younger than 5 years. These data reflect progress in child health but also underscore that child death, unlike parental or spousal death, is no longer an expected part of life. In industrialized nations, child death stands out as a singular tragedy and an increasingly uncommon event in the professional lives of clinicians, even those whose practice is exclusively pediatric.

Beginning in 2006, the Health Care Cost and Utilization Project has provided a national database of ED visits with the Nationwide Emergency Department Sample.⁶ Fewer than 3% of all ED patient visits were children younger than 1 year; deaths in that age group accounted for 1.9% of all ED deaths. Patients 1 to 17 years of age accounted for 18% of all ED visits and another 2% of ED deaths. In total, the percentage of ED deaths among patients younger than 18 years is less than 4%, occurring less than 1 per 15 000 ED visits. Because of the relative infrequency of child death in the ED setting, few emergency clinicians have extensive experience with child death.

Beyond the relative infrequency of this event, there are other formidable challenges in managing pediatric deaths, including the following:

- deciding when to terminate resuscitative efforts;
- deciding when not to initiate resuscitative efforts;
- managing painful or distressing symptoms in pediatric patients;
- ascertaining family wishes or identifying existing advance directives;
- managing family presence in the setting of attempted pediatric resuscitation;

- communicating with and caring for the family;
- asking families in crisis about potential organ donation or autopsy (when, how, who asks);
- effectively discharging forensic responsibilities in a child death, especially when it may be the result of intentional injury or neglect, while attempting to respond to the family's loss with compassion;
- withdrawing or withholding no longer beneficial medical interventions for children with chronic life span-limiting conditions;
- balancing respect for the newly deceased and bereaved with the opportunity for needed practical experience for practitioners and trainees to enhance skills to prevent potentially avoidable deaths in the future;
- resuming work after the emotionally difficult episode, needing to "pick up and move on to the next case"; and
- addressing the personal and clinical team emotions of anger, sadness, inadequacy, or blame that often result after caring for a child who dies in the ED.

The health care team's perceived obligation to maintain a calm and proficient demeanor can be at odds with the empathetic behaviors that are valued as most helpful to families facing the loss of their child. Because ED providers are so often exposed to critical events, they may have evolved a protective mechanism that normalizes the abnormal events they see every day, what Truog et al⁷ have called the "routinization of disaster." And yet what parents, caregivers, and family members who are enmeshed in this uniquely catastrophic experience report as important and beneficial to them is the kindness, empathy, and genuine caring of their child's care

providers. Given that they can anticipate that death will be the most common outcome of cardiac arrest in a child,⁸ ED providers must add care of bereaved family members to their list of skills and responsibilities.

Lack of training in critical health care communication, particularly in the compassionate delivery of difficult news, is pervasive even today throughout the spectrum of health care education, including nursing education, medical school, and residency.⁹ A large national survey published in 2003 indicates that role models and faculty at the medical school level are not equipped to teach these skills.¹⁰ Nurses may also be ineffective in communication.¹¹ In a 2008 AAP statement reviewing communication skills,¹² it was noted that "health care communication is currently learned primarily through trial and error." There is increasing evidence that communication skills can and should be taught and learned,¹³ and there are a number of strategies specific to the practice of emergency care.¹⁴ Communication skills are now recognized as a required core competency in nursing, medical student, and resident training accreditation criteria.¹² Emergency clinicians should support explicit training and skill building in communicating the difficult news that they may be called to deliver when a child dies in the ED.^{15,16} Results of parent surveys confirm that the delivery of the news of their child's death is extremely important to the long-term well-being of family members. Skill and compassion in conveying bad news may be the most powerful therapeutic tool clinicians can offer affected families.¹⁷ An approach to notifying parents of the death of their child in the ED is provided in Appendix 1. As with other uncommon but critical events, simulations of management of the death of a child can be conducted by ED staff to prepare them for this rare event.

FAMILY PRESENCE

Family presence in the ED has been defined as "the presence of family in the patient care area, in a location that affords visual or physical contact with the patient during invasive procedures or resuscitation events."¹⁸ Initial resistance to allowing family presence during attempted resuscitation was based on fears of litigation and concerns that the emotional burden for family members of watching resuscitation would create situations that would distract ED personnel, potentially interfere with effective resuscitation efforts, and only add to a family's burden of grief. These fears have been systematically studied and for the most part clarified or eliminated.^{19–21} Mangurten et al²² reported that 95% of the families they surveyed would again wish to be present and felt that it had been helpful to them, and no disruption of care was documented. In a similar study examining pediatric trauma resuscitation efforts, there also was no difference in time to milestones of care in trauma patients with or without family members present.²³ Studies and position statements reflect the increasing ability of emergency clinicians to effectively support family presence during attempted resuscitation in the setting of effective staff preparation, appropriate policy development and implementation, and, when staffing allows, providing designated personnel to attend to family members.

Family presence has received widespread endorsement. Supportive articles have appeared in the ethics literature, the resuscitation literature, and the general and pediatric emergency medicine and nursing literature.^{18–27} The Emergency Nurses Association (ENA), AAP, and ACEP have position statements on family presence.^{24–26} The revised jointly issued policy statement from the AAP, ACEP, and ENA recommends that all EDs

caring for children have a written policy regarding family presence.⁴

As a further indication of the acceptance of family presence during resuscitation attempts, the debate has turned from a goal of family presence during resuscitation to the goal of family presence at time of death pronouncement.²⁷ Strict adherence to this goal may result in the prolongation of otherwise futile resuscitative efforts. An alternative to prolonging an otherwise futile resuscitation attempt when family have not yet arrived may be to designate a family surrogate, a staff member whose job is simply to be with the child. When family members do arrive after their child has died, they should be assured that their child was not alone at the time of death.

NONINITIATION AND TERMINATION OF RESUSCITATION ATTEMPTS

Deciding when to terminate resuscitation efforts or not to initiate them at all ranks among the most difficult tasks facing the emergency health care team caring for a critically ill or injured infant or child.^{28–30} Although these actions are frequently described as ethically indistinguishable, they may feel quite different in the moment of decision. Further complicating these decisions is a lack of objective data on which to base guidelines, a desire to allow for family presence, the hope to increase potential for organ donation, and provider distress with the tragedy of the death of a child, any of which may contribute to initiation of or persistence in likely futile resuscitation efforts. Differences between general and pediatric emergency physicians in time until termination of resuscitation efforts on a child were first described by Scribano et al,³¹ noting that pediatric-trained ED physicians reported being twice as likely to terminate efforts if there was no return of spontaneous circulation after 25 minutes. The authors speculated

that some of the observed differences between general and pediatric emergency physicians were more related to provider distress than to a lack of familiarity with guidelines.

Although improved clinical outcomes have been reported since instituting new Pediatric Advanced Life Support/American Heart Association guidelines for defibrillation and for chest compressions, a 2008 review of advances in pediatric resuscitation states that there is not sufficient evidence to base a recommendation for duration of resuscitation efforts in all situations.⁸ In particular, findings of better-than-anticipated survival from prolonged cardiopulmonary resuscitation (CPR) followed by extracorporeal membrane oxygenation initiated for children who experienced cardiac arrest in the PICU cannot easily be extrapolated to the ED setting.³² Criteria for termination of resuscitation are not discussed in the 2009 review article by Topjian et al,³³ and at this time there are no universal criteria for termination of resuscitation efforts in children. The 2010 Pediatric Advanced Life Support guidelines point out that clinical variables associated with survival include length of CPR, number of doses of epinephrine, age, witnessed versus unwitnessed cardiac arrest, and the first and subsequent rhythm. None of these associations, however, predict outcome. Witnessed collapse, bystander CPR, and a short interval from collapse to arrival of professionals improve the chances of a successful resuscitation.³⁴

Likewise, in the out-of-hospital setting, there are no nationally accepted guidelines for noninitiation of resuscitation or termination of resuscitation that apply to children. The National Association of EMS Physicians has criteria for adults who experience traumatic or nontraumatic cardiac arrest, but these guidelines explicitly were not applied to children. Even with adults, however, the decision to

make an on-scene pronouncement versus transport in settings of probable futility may be driven more by perceived family needs and provider comfort.³⁵ The little evidence that exists, however, speaks to the family benefit of stopping resuscitation; at least 2 studies in adult patients indicate that families may in fact adjust better after pronouncement on scene than with transport to a hospital.^{36,37} No such data exist for children in the United States, but a Swedish study in adolescents with sudden cardiac death is supportive of pronouncement on scene as an option on the basis of parental report.³⁸ However, Hall et al³⁹ noted that paramedics are far more uncomfortable with termination of efforts in the field for a child than for an adult. Therefore, a child or infant may be transported to the hospital even though the resuscitative efforts may be futile, in order to provide a setting with better resources for support of the family and providers.

The situation of unanticipated birth of an extremely preterm infant at the limit of viability presents yet another example of the dilemmas regarding initiation and termination of resuscitation efforts, made more complex by evolving criteria and conflicting opinions about outcomes for increasingly immature live-born fetuses.^{40,41} Although factors such as gender, antenatal steroids, and single or multiple birth all affect outcome, the factors most commonly used to assess viability and to predict outcome are birth weight and estimated gestational age; however, these “simple” data points may, in fact, be difficult to determine with any accuracy in the ED setting. When such information is available, many institutional practices reflect the policy described in Tyson et al,⁴² who suggested that infants born at 22 weeks’ gestation and less not be subjected to resuscitation efforts, that infants born at 24 weeks’ gestation or more should

all receive attempted resuscitation, and infants born at a gestational age between these ages should undergo attempted resuscitation only with parental agreement. The recommendation of parental agreement is consistent with the 2010 AAP/American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care for neonatal resuscitation,³⁴ which serves as the basis for the *Neonatal Resuscitation (NRP) Textbook, Sixth Edition*,⁴³ and which cautions interpretation within local policy but advises noninitiation of resuscitative efforts for infants born at a gestational age of less than 23 weeks, who are born weighing less than 400 g, or who have visible lethal anomalies, such as trisomy 13 or anencephaly. The Neonatal Resuscitation Program (NRP) guidelines further suggest that efforts be terminated if, after 10 minutes of effective resuscitative efforts, the infant has no spontaneous heartbeat.

In the absence of precise determination of gestational age and weight, the guidelines developed for antenatal counseling by Batton et al⁴⁴ may prove useful in the ED: namely, that if the clinical team believes that there is no chance of survival, resuscitation is not indicated and should not be initiated; if the team believes that a good outcome is very unlikely, then parents should be engaged in the decision-making process and their preferences should be respected; and if the team's assessment is that a good outcome is reasonably likely, resuscitation should be initiated and its benefit should be continually reassessed, in consultation with the parents. Alternatively, if neonatal specialists are readily available to the ED, resuscitation can be attempted until they can participate in the decision to continue. Comfort care should be provided for all infants, regardless of the goals of care; improved neurologic and physiologic outcomes from comfort

care are clear. Comfort care is of particular importance as well for infants for whom resuscitation is not initiated or is not successful as well as for their families; care provided at the end of life is remembered by the bereaved for the rest of their lives. Nursing care of the dying infant includes comfort care for the family. Nursing guidelines from other venues, such as the NICU, can provide tools for ensuring that families have the opportunity to create memories that will not only help them with their immediate pain but also comfort them for a lifetime.⁴⁵ These recommendations are in accord with the most recent NRP guidelines.⁴⁶ In any given ED, policy regarding initiation and termination of resuscitation attempts on the extremely preterm newborn infant should be developed in conjunction with perinatal subspecialists who are most knowledgeable about resources and outcomes in that region and in accordance with NRP recommendations.

REQUESTING ORGAN DONATION

Broaching the subject of organ donation after the death of a child in the ED can be an intimidating task. However, recent studies have indicated that families are more often appreciative than offended or overwhelmed by such requests when they are approached with sensitivity by skilled staff and with attention to the optimal timing.⁴⁷ US federal regulations require that the regional organ procurement organization (OPO) be contacted for all deaths and impending deaths so that their representatives can become involved in a timely manner.⁴⁸

The patient who dies in the ED often is not a candidate for solid organ donation but may still be a candidate for donation of tissue, including corneas, heart valves, skin, bone ligaments, and tendons. There is little published literature regarding tissue donation

requests when a cardiac death occurs.⁴⁹ Therefore, best practices for request of tissue donation have been extrapolated from the organ consent literature. Likewise, there is little information about best practices specific to donation of tissue or organs from a deceased child.^{50,51} Availability of suitable donors continues to be the major limiting factor for growth in organ transplantation, especially in pediatric recipients, because the size of the organs is a critical aspect of the match process. Although studies have shown that family members' decisions about organ donation are influenced by many factors, including whether the deceased's donation intentions are known, parents/caregivers of young children usually must make a donation decision without any direct knowledge about their child's wishes. Donation can be perceived by families and providers alike as a way to salvage some meaning from an acute, unanticipated, and tragic loss, although there is literature that calls that perception into question.^{52,53} Timely referral and the use of trained personnel in organ procurement is critical to ensure that a rushed approach regarding organ donation is avoided with the family. Although the process of organ procurement may start in the ED with the admission of a critically injured child, at present best practice suggests that conversations regarding solid organ donation not be initiated in the ED if a patient is going to be admitted to the hospital and that consent for donation is much more common when an OPO representative is able to assist the care team in presenting this option to the family. Consulting OPO staff while the child is in the ED may provide guidance for the best timing. When a child dies in the ED, any exploration of family wishes regarding tissue donation should follow at some time removed from the news of the child's death but optimally by an OPO staff member who has become familiar to the family during their brief

stay. Ideally, supportive staff, such as a social worker, chaplain, and/or child life specialist, should be present during any request.⁵⁴

AUTOPSY

Autopsy requirements and standards vary by state. Emergency care providers should be aware of the laws that govern postmortem practice in their state and provide information to the family accordingly. The medical examiner or coroner should be notified, because the majority of ED deaths in most states will be under his or her jurisdiction. Hospitals may establish policies and procedures in collaboration with the medical examiner's or coroner's office for handling bodies after death in the ED. In the event that the medical examiner or coroner declines autopsy, the ED physician may recommend autopsy and consult the hospital pathologist. Autopsy is generally valued for its ability to provide additional diagnostic and epidemiologic data; however, Feinstein et al⁵⁵ argued for a family-centered analysis of benefits derived from autopsy. They noted that autopsies also yield information that may inform parents' or siblings' subsequent reproductive or other health choices or other information pertinent about the deceased child, may assist with quality assurance and improvement, and may provide general knowledge that benefits both families and the clinical care teams. Framed in this fashion, parents may be grateful for the request. Emergency clinicians who understand these additional potential benefits of autopsy for families may be more comfortable in discussing it with them.

Medical Documentation and Notification of the Child's Medical Team

It is the responsibility of the emergency health care team to ensure prompt notification of the primary care pro-

vider, child's medical home, and other appropriate members of the child's medical team, including out-of-hospital providers, in the event of a child's impending death or death in the ED. Families expect that their primary care provider will be aware of their child's death, and the task of notifying the medical home and others of a child's team should not fall to the family. Their loss may be further compounded if they do not hear from their child's providers or there is no outreach or acknowledgment from those who have cared for the child over time. If the child's medical team is not aware, for instance, routine reminders for well-child visits or immunizations might continue. If the child had subspecialty providers, the same guidelines may hold true; and in some conditions and cases, the connection between subspecialist and family may be stronger than that between family and medical home.

In addition, such communication is beneficial for the ED team, to provide helpful background information and to know that bereaved families will be followed by caregivers who have known them before the child's death. The medical home may supply the ideal staff to provide a presence at memorial services, sibling support, and follow-up review of any autopsy findings. Routine follow-up meetings happen infrequently for families of children who die in the ICU setting,⁵⁶ and the frequency of routine follow-up meetings with ED staff is unknown. Autopsy review has benefits not only for the family but also for medical personnel as well, and further information is needed about the impact for families and health care team members on providing this practice.

The development of a policy and procedure for handling of the body may include the following:

- a death packet and checklist to ensure that all appropriate notifications are accomplished;
- documentation of release of valuables;
- documentation of release of the body;
- notification of a funeral home;
- completion of the death certificate in accordance with state law, as applicable; and
- notification of the child's primary care provider.

SUPPORTING THE WORK OF CHILD FATALITY REVIEW TEAMS

Death review is a potent tool for understanding and preventing avoidable deaths. Although child fatality review teams (CFRTs) were first established to review suspicious child deaths involving abuse or neglect, CFRTs have expanded toward a public health model of prevention of child fatality through systematic review of child deaths from birth through adolescence. Child fatality review is supported at the federal level by the National Center for Child Death Review, funded by the Maternal and Child Health Bureau since 2002; by 2005, all but 1 state reported providing state or local review of child deaths. In 2009, 27 states were contributing to the national database maintained by the National Center for Child Death Review.⁵⁷

Child fatality review operates on the principles that a child's death is a sentinel event, the review of which can lead to an understanding of risk factors when based on a multidisciplinary and comprehensive review. Emergency clinicians can support this mission at several levels: by notification of their local or state team when a child death occurs; by advocating for access to ED records regarding the case when legislation, regulations,

and policies allow the confidential exchange of information; and by active participation of ED staff on a particular review or as standing members of the review team. Because most ED deaths will be medical examiner/coroner cases, notification of the CFRT will usually be ensured by that mechanism.

The National Center for Child Death Review recommends that local and state CFRT boards include an ED clinician as a standing board member.⁵⁸ When invited to attend a specific case review meeting, emergency clinicians should make every effort to attend, share information on a specific case and/or general information on ED practices and policies, and encourage improvements in systems and prevention. Emergency clinicians are important to CFRTs, because they can supply information on services provided to a particular child or family if seen in the ED as well as general information related to emergency care, including types of injuries and deaths, medical terminology, and concepts and practices specific to emergency care. They can further support team activities by providing the medical information needed for successful prevention campaigns and strategies. Simply documenting, in detail, the circumstances of a child's death allows the emergency clinician to play a powerful role in the prevention of disease and injury. Emergency health care providers should support training in optimal collaboration with CFRTs and in the documentation of circumstances of death, the completion of death certificates, and analysis of findings on physical examination that may shed light on the cause. The use of CFRT data may result in changes to child welfare systems, improvement in training and interagency protocols, and new legislation and regulations. The determination of the leading causes of preventable deaths has resulted in

implementation of prevention procedures (eg, child safety restraints and pool fencing) and prompt public policy discussion and action.

BALANCING FORENSIC RESPONSIBILITIES WITH COMPASSIONATE CARE

In 2009, an estimated 1770 children in the United States died as a result of inflicted injury or neglect. Nearly half of fatal child maltreatment cases occur in infants younger than 1 year, and 80% occur in children younger than 4 years. Any child death presenting to the ED may require consideration of maltreatment as a cause of death, especially when the history does not match the clinical presentation.⁵⁹ Although there is literature to support the need for training and resources for the responsible performance of forensic duties in the ED in situations involving the death of a child,^{60,61} there is little reported that describes the tension between health care providers and law enforcement that can sometimes result when the death is suspected to be the result of neglect or homicide. The emergency clinician is called to balance the needs for accurate forensic information with the compassionate care of the family whose child just died. In the focus on time-sensitive, potentially lifesaving interventions, medical staff may inadvertently destroy crucial evidence, creating the potential for conflict with law enforcement officials. In the acute care setting, it is often impossible to determine whether a potentially lethal condition has resulted from intentional or accidental causes, and the bereaved family should be offered access to their child, in accordance with local policy, while making every effort not to compromise patient and staff safety or evidence. Access to a forensic nurse examiner, who may have developed collaborative working

relationships with law enforcement professionals, may be beneficial.⁶² Forensic nurse examiners have been specially trained in evidence collection and the care of victims and secondary survivors and may provide another option for standardized expert care. They can be notified of a pending arrival of a pediatric patient in extremis, remain exempt from the actual resuscitative care, and provide an additional trained team member whose primary purpose is the preservation of evidence. Appendix 2 of this report offers a sample protocol for collaboration between health care providers and law enforcement in situations in which there is concern for intentional injury resulting in death.

PRACTICE ON THE NEWLY DECEASED

Studies from the previous decade have suggested that 47% to 63% of emergency medical training programs allowed the practice of procedures on the newly deceased to ensure the development and maintenance of skills for trainees and clinicians to benefit future patients; however, in the past, consent was rarely sought.⁶³ With the increasing frequency of family presence during resuscitative efforts, evolving sophistication of alternative methods of training such as simulation, and a growing sense among participants or observers that norms of decency are being breached, this practice is likely to be diminishing in frequency. Interestingly, consent for procedures on the newly deceased is sought and obtained more often in the NICU than in the ED, possibly because of the existence of a longer standing relationship and trust. The Society for Academic Emergency Medicine has taken the position that all emergency medicine training programs should develop a policy regarding practice on the newly deceased and make that

policy available to the institution, educators, trainees, and the public.⁶⁴ The ENA has issued a policy statement affirming the legitimate need to master critical and lifesaving procedures, to obtain consent, and to consider alternative teaching methods such as simulation.⁶⁵

FAMILY BEREAVEMENT

The *Emergency Department Bereavement Resource* manual from the National Association of Social Workers is a practical resource for optimal ED preparation for the death of a child in the ED.⁶⁶ The manual also offers practical suggestions for memory making and bereavement care in the ED after a child has died. Most families not present at the time of death felt that they should have received the news from an attending physician. Similarly, most felt that a follow-up call from providers who were present with them during and after the time of their child's death would be meaningful, although few reported receiving such a call.⁶⁷ Postmortem follow-up communication has been shown to be perceived as very positive by survivors of adult patients who died in an ED¹² and for bereaved parents of children who died in the PICU.⁶⁸ Parents recognize staff with whom they have had only this brief intense encounter as the last people to see their child alive, with whom they shared an overwhelmingly difficult event in their own lives, and therefore as important keepers of the memory of their child. It can be comforting to ED staff, who themselves mourn the death of child patients, to know that even small gestures of condolence such as a card or phone call can have a profound and positive effect on grieving families. A sample bereavement checklist for use in the ED is included in the Appendix 3 of this report.

Parents reported that they valued the care provided by physicians and other members of the emergency care team who were accessible, honest, caring, and able to speak in lay language at a pace that matched the parents' ability to process and comprehend. The pace of this information is necessarily accelerated in the emergency setting, but the family's need for continued access to providers, whether from the ED staff or from more familiar resources, is very likely the same. It is the responsibility of ED clinicians to ensure that families will receive follow-up from the most appropriate source for that family, which may indeed be the ED staff in some cases.

COLLABORATION WITH PEDIATRIC PALLIATIVE CARE SERVICES

Studies in children with known life span-limiting conditions report that between 3% and 20% of deaths in that population will occur in the ED.^{69,70} Because the ED remains part of the safety net of care for many children who are dying at home or who face a known life span-limiting condition, it is therefore sometimes the unanticipated venue for end-of-life care for such children. Increasingly, children with life span-limiting conditions may be cared for by local agencies and clinicians providing pediatric palliative care. Palliative care is a growing subspecialty within pediatrics, as evidenced by the recent creation of a Section on Hospice and Palliative Medicine within the AAP and recognition of the specialty of palliative care through a certificate of added qualification by the American Board of Pediatrics and other American Board of Medical Specialties boards. Palliative care services are not uniformly available, however, even at tertiary care or exclusively pediatric facilities. Nevertheless, as more

children are provided palliative care services, explicit and anticipatory collaboration between pediatric palliative care services and their corresponding EDs will likely improve care for such children. Many children receiving palliative care have had the opportunity to develop advance care plans. It can be very helpful for ED staff to have an understanding, in advance, of the hopes, concerns, and wishes that the child and family may have expressed. The emergency information form template developed by the Emergency Medical Services for Children program, in conjunction with the AAP and ACEP,⁷¹ includes advance directives that can be helpful in critical decision making with the family. Pediatric palliative care specialists can help families by anticipating which ED and EMS services will serve as entry points for their children and by sharing relevant medical history and care plan information with the EMS and ED personnel, with permission of the family. Similarly, when ED clinicians identify a child who might benefit from such a care plan, they may consider contacting pediatric palliative care resources to help develop such a plan for future potential ED visits. Pediatric palliative care teams can be a helpful resource for providing or identifying bereavement follow-up resources for individual families, for assisting to develop a consistent policy for bereavement follow-up from the ED, and for supporting ED caregiver gatherings and debriefings after the death of a child. An innovative project to integrate palliative care principles into emergency medicine practice provides additional resources on the Web site of the Center to Advance Palliative Care (www.capc.org). A guideline for developing a protocol for planned death in the ED of a child with a known terminal condition is included in Appendix 4.

THE CONCEPT OF A GOOD DEATH

The idea of a “good death” is a concept rarely discussed in the emergency medicine literature, and it is difficult to apply paradigms developed outside of the ED, mainly in the realm of adult palliative care, to the acute, unanticipated death of a child in the ED. The Institute of Medicine report on childhood death provides the following definitions for good and bad deaths:

“A decent or good death is one that is: free from avoidable distress and suffering for patients, families, and caregivers; in general accord with patients’ and families’ wishes; and reasonably consistent with clinical, cultural, and ethical standards. A bad death, in turn, is characterized by needless suffering, dishonoring of patient or family wishes or values, and a sense among participants or observers that norms of decency have been offended.”⁷²

Modern medicine has cultivated an unspoken belief that death is a failure on the part of the medical system, and the culture of the ED is perhaps most particularly vulnerable to this covert belief. A first step toward developing an understanding of what a “good death” might be in the ED setting is necessarily the acknowledgment that death is not avoidable. The knowledge and application of best resuscitation practices, whether in terms of applying interventions or appropriately withholding them, are required to know that a death was unavoidable. A second aspect of what might constitute a “good death” in the ED is caring for the survivors of the child’s death in a way that affirms their trust, allowing them to understand the events leading up to death, to exert some control in the situation, and to say goodbye to their child in whatever way is meaningful to them. These tasks have been identified as critical to the well-being of a bereaved family and can be supported by the clinical team with practical assistance, information, and compassion.^{73,74}

CARE FOR THE CARE PROVIDER

Finally, how ED staff care for each other as members of an interdisciplinary team of care providers is a third essential aspect of a “good death.” All ED staff benefit from training in communicating bad news, in managing the families’ expected emotional responses, and in understanding and managing the emotional responses in ourselves and our colleagues. It is important to offer voluntary defusing or debriefing to staff after critical incidents, such as the death of a child, although it is often challenging to find a time to gather those who wish to participate. However, Treadway’s⁷⁵ compelling essay, “the Code,” suggests that even a simple acknowledgment at the bedside after the death of a patient may be beneficial to staff. She speculates that there may be a healing potential to closing rituals that are communal rather than private. An example of a brief closing ritual is provided in Appendix 5 of this technical report.

SUMMARY

The death of a child in the ED remains one of the greatest challenges for ED staff. Since the original technical report,² the science of resuscitation has advanced and national organizations have strengthened position papers to facilitate family-centered care, including family presence during resuscitation. Concepts of the medical home, child fatality review, and pediatric palliative care have evolved. Hospitals can adopt policies and practices that provide guidelines for the care of the patient, family members, and care providers. These policies should incorporate family presence, termination of resuscitation efforts, bereavement protocols, and evidence preservation. It is important to address compliance with laws governing jurisdiction after death and the means to support staff when a child dies in the ED.

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APPENDIX 1: GUIDELINES WHEN NOTIFYING A FAMILY OF THE DEATH OF THEIR CHILD IN THE ED

Modern medicine has cultivated an unspoken belief that death is a failure on the part of the medical system, and the culture of the ED is perhaps most particularly vulnerable to this covert belief. It is helpful to acknowledge that death is not avoidable in many of the conditions we are called on to treat in the ED. When it feels as if all you have left is the terrible news of a child's death, in fact your presence, empathy, practical assistance, and information enable you to provide a bereaved family with essential assistance that they will need to adjust to their loss. Families who lose a child through an acute and unanticipated event have at least these tasks to address: they need to understand the events leading up to death, to feel that they can exert some control over a universe suddenly completely out of control, to be able to say goodbye to their child in some meaningful way, to be able to make sense of the death, and to be able somehow to carry the child forward in their lives as they negotiate a new and ongoing relationship with the child they have lost. Your role in telling the family about the death of their child can help them toward accomplishing these tasks.

Preparation

First, take a moment for self-reflection, to acknowledge your own feelings (inadequacy, guilt, sadness, anger, fear) and perhaps to find a colleague with whom to share those emotions beforehand. Take note of those emotions, whatever they are, and then, without comment or criticism, allow yourself to put them aside.

Think for a moment how you might act if a dear friend told you that he or she had just received terrible news: what would you do, as one human

being to another? Use that as a model of how best to help this family with the news you have to give them. Strive to be a kind and steadying presence.

Families take it as a mark of respect and an indication of how importantly we view their loved one when the responsible attending physician is the one notifying the family.

Know and use the child's name.

Ensure that the right family members have been gathered and available resources have been assembled (which might include chaplaincy, social work, child life, or outside family supports, such as family chaplain or primary care provider).

Use a skilled medical interpreter, not a family member, for any translation needs. If using a family member is the only recourse, acknowledge to the family interpreter how difficult it is to hear bad news and then have to share that news.

Choose an appropriate setting that is quiet, provides privacy, and has enough places to sit for all who are needed to be present, with water and tissues available. Make yourself available and presentable (turn off beeper, check appearance, be sure to sit down).

Have a written copy of your name and contact information available. You may want to include other staff member names as well, such as the primary nurse, the social worker, child life, etc.

Steps in the Process

Introduce yourself and your role, shake hands or touch family members if appropriate, sit down at eye level.

If appropriate, determine what the patient and family understand about the present situation. "Please tell me what you already know about what has happened to [child's name]."

Prepare them with fair warning: "I am so sorry that I have to give you this bad news." Hold them in your gaze.

Continue to hold them in your gaze and inform them of the death in a direct manner, using the words "die" or "death." For example, "We did everything we possibly could, but [child's name] has died."

Sit quietly and allow the family to respond. The entire range of human emotion is possible at this moment. Resist the temptation to fill this silence and allow the family to be the first to break the silence.

Hear and respond to the family and patient's emotions, and provide additional information at the family's or patient's pace. (Avoid statements that begin with "I know you must be feeling very....") Instead, acknowledge what you see or feel. "I cannot imagine how difficult it must be to hear this news."

Solicit questions, assess understanding, and follow the family's lead. "I have given you such terrible news. Would it help to see [child's name] now, or do you have any questions for me, anything that I can explain better?"

Families may not ask but may be comforted to know that their child did not suffer, so if it is possible to give that reassurance, do so.

Any bad outcome with a child is inextricably linked to parental feelings of guilt. If it is possible to give reassurance about the family role in the event or note any contribution they made that was helpful, do so. "I don't see any way this accident could have been anticipated." Or, "Your information about her medical problems in the past was essential information for us."

Be prepared to repeat information, because it is nearly impossible to take in new information when under the kind of stress that a family member would be feeling at this time. Nevertheless, understanding and sometimes even reconstructing the events that led up to their child's death are often an

essential part of family acceptance and well-being after the loss of a child. Even simple information about what will happen next or what choices they have will be helpful. Your ability to give the information they need and ask for, at the pace they require, can be one of the most therapeutic “procedures” you can perform.

Offer assistance in helping the family to share this news with others, such as siblings or young children. Let them know that you will be notifying the child’s primary care provider and any relevant specialists.

Give your contact information in written form and let the family know of any follow-up arrangements, such as a call from the ED social worker in the next day or so.

Consider writing a condolence note to any family to whom you have had to give the news of their child’s death in the ED. It is an act with remarkable potential for healing.

SELECTED RESOURCES

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APPENDIX 2: SAMPLE PROTOCOL FOR COLLABORATIVE PRACTICE WITH HOMICIDE INVESTIGATION ON SITE IN ED

City Police Department Homicide Division

The following procedures are to be used by city police officers when responding to a death involving a child

age ≤ 6 years at an area hospital. The procedures are designed to maintain the integrity of the police death investigation while permitting the hospital staff the continued use and management of the ED. The procedures also recognize the rights of the family to have access to their child to grieve the loss. Compassion and cooperation are key in handling these situations, and officers should always exercise good judgment in their decisions as it relates to child death investigations. If there are any questions concerning these procedures, please contact your city’s Homicide Division for resolution and guidance. A sample algorithm is provided in Appendix 2A.

Child Death Investigation Procedures

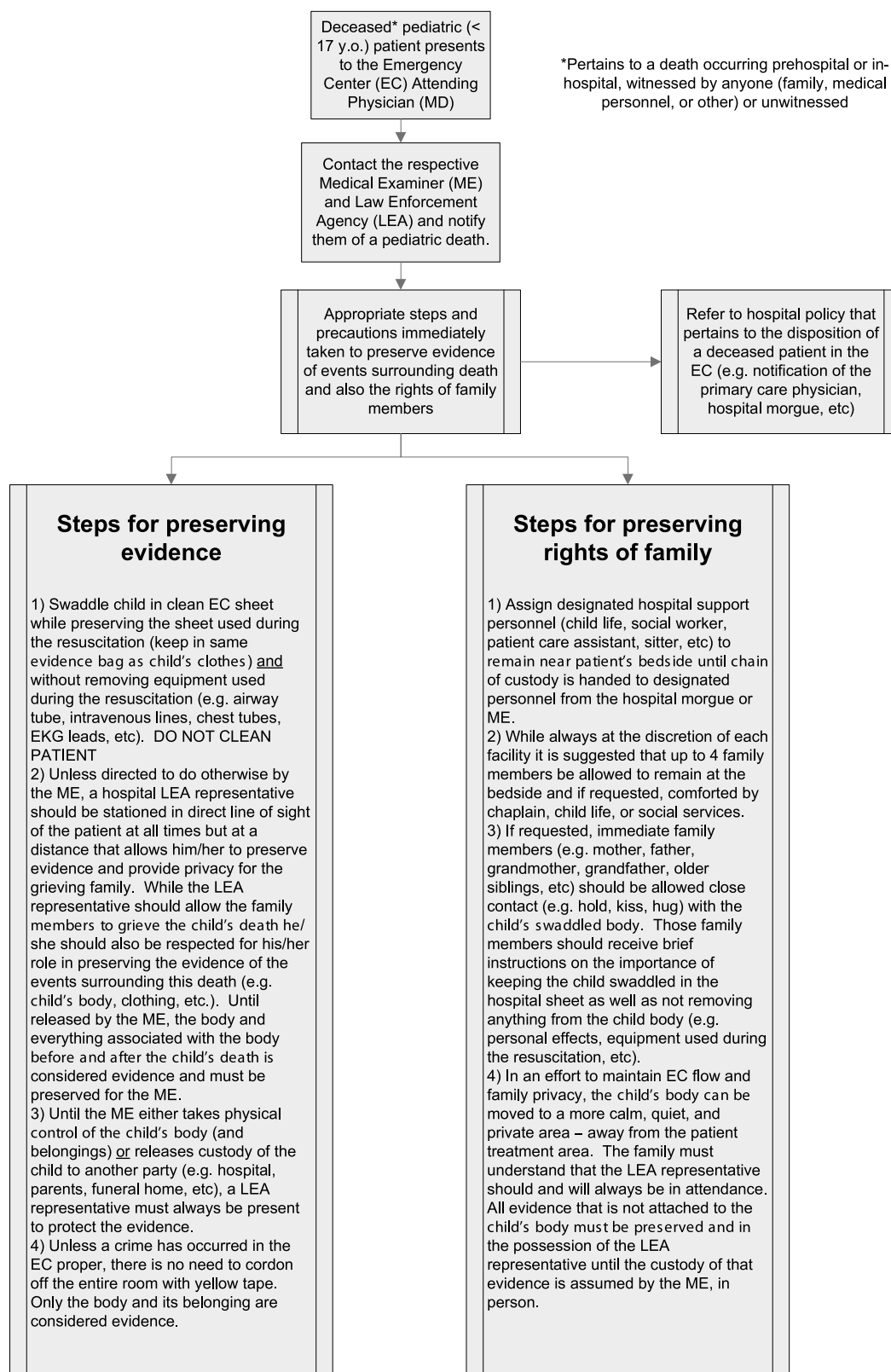
- When notified of a child death at a local hospital, responding officers, whether on-duty or working security, will ensure that the Homicide Division is notified immediately of the death. As many details as possible of the death should be obtained and relayed to the Homicide Division, such as name of the child, location the child was transported from, who transported the child, and any medical history or condition known.
- If the child was transported to the hospital from an outside location, make sure an on-duty unit is dispatched to the location to secure the scene as part of the investigation. In most instances, on-duty units will already be involved. If not, the Homicide Division desk officer can assist in getting a unit sent to the transporting location.
- Allow hospital staff to move the child out of the ED treatment room to another room or morgue. The officer will stay with the child and “observe and record all observations” until the arrival of the homicide

investigators. Remember, the ED room IS NOT a crime scene; the evidence for the investigation is the body of the deceased.

- Immediate family members should be allowed access to grieve the loss of their child. The officers should remain with the child and the family members until the arrival of the homicide investigators. Hospital staff should swaddle the child’s body in a clean sheet while preserving the sheet used during resuscitation efforts and without removing equipment used during the resuscitation efforts.
- If there are “obvious” signs of trauma, such as broken bones, significant bruising, or other injury indicating foul play in the child’s death, the child’s body may be removed from the ED treatment room into a secure room or morgue pending the arrival of homicide investigators. In this instance, there should be no contact with family members and the child’s body should be secured as evidence. Any questions about this should be directed to the Homicide Division.

In cases of child deaths in which the child has a history of medical problems and treatment of a long-term illness that make it clear that the death does not involve foul play or negligence, homicide investigators may elect not to respond or conduct the investigation. In those instances, the officer is responsible for preparing the report and conducting the scene investigation. This decision is made by the Homicide Division duty lieutenant, and all decisions about the homicide response should be directed to him or her.

Any questions about the handling of child death investigative procedures at area hospitals should be directed to the City Police Homicide Division.



APPENDIX 2A

The deceased patient in the emergency center (EC) decision tree: balancing the rights of survivors with the necessary preservation of evidence (courtesy Paul Sirbaugh, MD, personal communication). EKG, electrocardiogram.

APPENDIX 3: SAMPLE RESOURCE GUIDE FOR ED BEREAVEMENT CHECKLIST AND MEMORY BOX

This resource is meant to help guide you in the next stage of your care for a bereaved family.

Your interventions and caring have the potential to bring much comfort and meaning to this family and significantly influence their grieving.

Sections I and II: Demographics/Information

Please complete the Bereavement Checklist, which will help with bereavement follow-up and staff support. Please place the finished checklist *in the designated location/or to the designated personnel*.

Section III: Family Members

Our ED offers the option of family presence during invasive procedures and resuscitation. A family facilitator, nurse, social worker, or physician should assess the family before being with the patient. The family facilitator should accompany the family to provide support and medical explanations.

For many families, this may be their first experience of death, and they will not know what is permissible or expected. They may not know what will be comforting or healing to them now or in the future and will look to us for guidance. You might say something like “Many families have told us that they were comforted by the memory of talking to the patient or holding or touching their loved one—would you like to be able to do that?” Whenever possible, it is desirable to offer family private time (accompanied or unaccompanied as they request) to be with their loved one after death.

Family members may arrive after the child’s body has been transported to the morgue and the morgue staff are not available. If appropriate, the resource nurse should notify the nursing

supervisor and police and security to bring the family to the morgue and identify supportive staff (social work, nursing, physician) to accompany family members.

Section IV: Memory Box

The memory box is a legacy gift that can be given to family members after the death of their child. It can include hand and foot molds made out of model magic clay, handprints and footprints using inkless wipes and paper, a lock of hair, photographs if the family so chooses, and any mementos the child came with (clothes, shoes, jewelry, hospital band, hair accessories, etc). The directions for making the clay imprints and inkless prints are in each bereavement box, along with the necessary tools to make them. All of the memory box supplies (including resources and blankets) are kept _____. Sometimes families (including siblings) like to be involved in making the ink prints and clay imprints, so this opportunity should be offered to the family. More than 1 box can be made for families if the parents/caregivers live separately. Extra copies of the ink prints can be made using the copier for additional family members. If the family does not want to take the box home with them at this time, please let them know it will be kept at the hospital in case they change their mind over the next several months. Please lock the box in the valuables cabinet if the family does not want to take it home at this time.

Section V

Notification

Most ED deaths are considered a mandatory autopsy by the medical examiner. If the medical examiner decides to accept the case while the family is still in the ED, the family should be told, because it can affect funeral arrangements. Please note that the OPO will automatically be notified by

the hospital when the death certificate is completed. Studies have shown that professional OPO staff members are more skilled (even more than seasoned ED staff) at discussing potential organ donation with families, so you should defer all discussion of organ donation to OPO staff. In pediatric deaths of uncertain etiology, such as suspected sudden unexpected infant death or abuse, it is sometimes helpful to arrange with the medical examiner that the autopsy be performed at a facility with specific pediatric expertise.

Aftercare of the Deceased

To the extent possible, we should respect and support faith-based or cultural traditions around treatment of the deceased after death. For instance, for some traditions, it is not acceptable to leave a deceased person unattended, whereas for others it may not be acceptable for the child’s body to be handled by someone of the opposite sex. You might ask “Does your family culture or faith tradition give you guidance about what should happen after someone dies? We would like to support you in that if we can.” For many families, particularly those dealing with the loss of a child, the thought of leaving the deceased child alone in the morgue is very difficult. If a medical examiner autopsy is declined, it is sometimes possible to arrange for the funeral home to pick up the child’s body from the ED. This procedure involves the family identifying funeral home, attending physician completing a death certificate, and admitting staff processing the paperwork.

APPENDIX 4: GUIDELINES FOR DEVELOPING A PROTOCOL WHEN THE ED BECOMES THE UNANTICIPATED VENUE FOR END-OF-LIFE CARE FOR A CHILD WITH A TERMINAL CONDITION

Although the ED is not a common venue for end-of-life care of children with

SECTION I:

Patient Name _____

MR# _____ Date _____

Date of Birth _____

Diagnosis _____

Brief history surrounding

death _____

Family contact information (name, relationship,

contact#) _____

Primary RN _____ Attending MD _____

Section II: NOTIFICATION (please note, organ bank is notified by admitting staff: please defer discussion of organ donation to organ bank staff)

	Phone or Pager #	Name
Charge Coordinator		_____
Psychiatric Nurse Specialist		_____
Social Worker		_____
Child Life Specialist		_____
Chaplaincy		_____

Medical Examiner's Office _____

Section III: FAMILY MEMBERS:**Key: Father=F Mother=M Sibling=S Spouse=SP Child=C Significant Other=SO**

Family presence during resuscitation?	F M S SP C SO	
Not offered? Why?	F M S SP C SO	_____
Not accepted? Why?	F M S SP C SO	_____
Present with patient after death?	F M S SP C SO	
Touched child after death?	F M S SP C SO	
Held child after death?	F M S SP C SO	
Assisted with aftercare?	F M S SP C SO	

Section IV: GENERAL INFORMATION FOR PEDIATRIC PATIENTS**MEMORY BOX**

Baby blanket
 Box given to _____ or box locked in valuables cabinet
 Instant photo with permission
 Hand mold and/or prints
 Lock of hair in small bag
 Bereavement resources
 Any personal articles/artifacts
 Siblings names/ages _____

Section V: AFTERCARE OF THE DECEASED/DOCUMENTATION

Prepare child's body for morgue/funeral home (if autopsy leave tubes in place)
 Cover with clean blanket (adult or baby bereavement blanket to go with family)
 Nursing note to document date/time of death
 MD note to document date/time of death
 Assist family with information about funeral arrangements
 Informational booklets given to family

***Please place this finished checklist _____.

APPENDIX 3A

Bereavement Checklist. MR, medical record.

known terminal conditions, as many as 10% of children with complex medical conditions will die in the ED setting. Some of those children will have advance care plans and family may have hoped that their child could die at home. However, in many locales, there are not resources to provide hospice or end-of-life care in the home setting for children, and many parents/caregivers report that even when the child's death is anticipated, the presence of medical personnel at the time of active dying is critical to their support and comfort.

In developing individual institutional guidelines for the care of a child with a terminal condition who presents to the ED actively dying, consider input from the following stakeholders if available:

ED physician, nursing and administrative staff
Hospital palliative care
Chaplaincy
Social services
Child life services
Pharmacy (for rapid access to pharmacologic management of symptoms)
Admitting staff
Case management
Hospitalist service (for consideration of rapid/direct admission or transfer to an alternate site)
Community-based palliative care providers

Consideration should be given to clarification of the means to facilitate the following:

- Assessment of the family's wishes, including resources needed for the child to return home to die

- Expeditious symptom management (respiratory distress, delirium, seizures, pain, control of secretions, control of bleeding)
- Provision of a private space in the ED, with the option for family to hold child if feasible and desired
- Contacting all existing care providers on the child's team
- Identification of alternate venues of care, including inpatient service, residential hospice, home
- Memory making by family members
- Ensuring bereavement follow-up, whether by ED staff or other
- Ensuring debriefing mechanism for ED and EMS staff.

In the event that a child with an advance care plan presents to the ED in medical crisis:

- Provide all comfort measures.
- Acknowledge all family members present
- Ask about current goals of care (eg, maximizing comfort versus attempting to prolong life)
- Engage in rapid resolution of severe distress and manage ongoing symptoms such as pain, secretions, seizures, delirium, respiratory distress, bleeding
- Provide private location as possible, with option for family to hold child if feasible and desired
- Ask family regarding their wishes at this time.
- For example: "We will keep [your child] safe and comfortable. If this

is her time to die, what can we do to support you and your family best? Is there anyone (physician, faith community, family, etc) you would like us to contact?"

- Contact primary and specialty care providers
- Notify OPO if indicated
- Assess optimal venue for care if death is not imminent: for example, "If your hope would be that your child could be at home when he/she dies, what resources will you need for your child to be safe and comfortable there? If we cannot secure those in your home setting, we will try to find the best place for you to be as a family. Would you like us to arrange for your child to be admitted to the pediatric floor/residential hospice?"
- Provide opportunity for memory making, any rituals to support faith-tradition or cultural practice, and family leave-taking
- Identify ED and EMS staff involved in care for participation in staff debriefing and in any bereavement follow-up for family.

APPENDIX 5: EXAMPLE OF A CLOSING RITUAL AFTER THE DEATH OF A CHILD IN THE ED

"I thank everyone here for their efforts to save [this child's name] life. Please take a moment in silence with me now to acknowledge our sorrow at his or her passing... In his or her name [touching the child if appropriate] may we each be rededicated to our work."

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Emergency Contraception: Addendum

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- *Policy Statement*

POLICY STATEMENT

Emergency Contraception: Addendum

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COMMITTEE ON ADOLESCENCE

This is an addendum to the American Academy of Pediatrics Policy Statement “Emergency Contraception” (*Pediatrics* 2012;130(6): 1174–1182).

In April 2013, Judge Edward Korman of the US District Court of Eastern New York directed the Food and Drug Administration (FDA) to lift the ban on over-the-counter availability of levonorgestrel-based emergency contraceptives without a prescription and without point-of-sale or age restrictions. In June 2013, the Obama administration withdrew its appeal to the Korman ruling, and the FDA allowed the 1-pill formulation Plan B One-Step (Teva Women’s Health Inc, Frazer, PA) to be made available on the shelf without age restriction in the United States. The FDA granted Plan B One-Step 3 years of exclusive rights to sell the product without an age restriction. One-pill generic versions will likely be allowed to be sold on the shelf next to Plan B One-Step, but these products will require age verification and will not be sold to those younger than 17 years without a prescription. The 2-pill formulations of levonorgestrel-based emergency contraceptives will remain behind the pharmacy counter and will also not be sold to those younger than 17 years without a prescription.

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Equipment for Ground Ambulances

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- *Policy Statement*

POLICY STATEMENT

Equipment for Ground Ambulances

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AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA, EMERGENCY MEDICAL SERVICES FOR CHILDREN, EMERGENCY NURSES ASSOCIATION, NATIONAL ASSOCIATION OF EMS PHYSICIANS, AND NATIONAL ASSOCIATION OF STATE EMS OFFICIALS

On January 1, 2014, the American Academy of Pediatrics, American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and National Association of State EMS Officials coauthored a joint policy statement, "Equipment for Ground Ambulances" (*Prehosp Emerg Care*. 2014;19[1]:92–97). The full text of the joint policy statement is available at: <http://informahealthcare.com/doi/full/10.3109/10903127.2013.851312>. Copyright © 2014 Informa Plc.

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Evaluating Children With Fractures for Child Physical Abuse

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- *Clinical Report*

CLINICAL REPORT

Evaluating Children With Fractures for Child Physical Abuse

Emalee G. Flaherty, MD, Jeannette M. Perez-Rossello, MD, Michael A. Levine, MD, William L. Hennrikus, MD, and the AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON CHILD ABUSE AND NEGLECT, SECTION ON RADIOLOGY, SECTION ON ENDOCRINOLOGY, and SECTION ON ORTHOPAEDICS, and the SOCIETY FOR PEDIATRIC RADIOLOGY

KEY WORD

fractures

ABBREVIATIONS

CML—classic metaphyseal lesions
CPR—cardiopulmonary resuscitation
CT—computed tomography
OI—osteogenesis imperfect

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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Fractures are common injuries caused by child abuse. Although the consequences of failing to diagnose an abusive injury in a child can be grave, incorrectly diagnosing child abuse in a child whose fractures have another etiology can be distressing for a family. The aim of this report is to review recent advances in the understanding of fracture specificity, the mechanism of fractures, and other medical diseases that predispose to fractures in infants and children. This clinical report will aid physicians in developing an evidence-based differential diagnosis and performing the appropriate evaluation when assessing a child with fractures. *Pediatrics* 2014;133:e477–e489

INTRODUCTION

Fractures are the second most common injury caused by child physical abuse; bruises are the most common injury.¹ Failure to identify an injury caused by child abuse and to intervene appropriately may place a child at risk for further abuse, with potentially permanent consequences for the child.^{2–4} Physical abuse may not be considered in the physician's differential diagnosis of childhood injury because the caregiver may have intentionally altered the history to conceal the abuse.⁵ As a result, when fractures are initially evaluated, a diagnosis of child abuse may be missed.³ In children younger than 3 years, as many as 20% of fractures caused by abuse may be misdiagnosed initially as noninflicted or as attributable to other causes.³ In addition, fractures may be missed because radiography is performed before changes are obvious or the radiographic images are misread or misinterpreted.² However, incorrectly diagnosing physical abuse in a child with noninflicted fractures has serious consequences for the child and family. To identify child abuse as the cause of fractures, the physician must take into consideration the history, the age of the child, the location and type of fracture, the mechanism that causes the particular type of fracture, and the presence of other injuries while also considering other possible causes.

DIFFERENTIAL DIAGNOSIS OF FRACTURES**Trauma: Child Abuse Versus Noninflicted Injuries**

Fractures are a common childhood injury and account for between 8% and 12% of all pediatric injuries.^{6–8} In infants and toddlers, physical

abuse is the cause of 12% to 20% of fractures.⁹ Although unintentional fractures are much more common than fractures caused by child abuse, the physician needs to remain aware of the possibility of inflicted injury. Although some fracture types are highly suggestive of physical abuse, no pattern can exclude child abuse.^{10,11} Specifically, it is important to recognize that any fracture, even fractures that are commonly noninflicted injuries, can be caused by child abuse. Certain details that can help the physician determine whether a fracture was caused by abuse rather than unintentional injury include the history, the child's age and developmental stage, the type and location of the fracture, the age of the fracture, and an understanding of the mechanism that causes the particular type of fracture. The presence of multiple fractures, fractures of different ages or stages of healing, delay in obtaining medical treatment, and the presence of other injuries suspicious for abuse (eg, coexisting injuries to the skin, internal organs, or central nervous system) should alert the physician to possible child abuse.

Child's Age and Development

The physician should consider the child's age and level of development. Approximately 80% of all fractures caused by child abuse occur in children younger than 18 months,¹² and approximately one-quarter of fractures in children younger than 1 year are caused by child abuse.^{1,9,13–15} Physical abuse is more likely to be the cause of femoral fractures and humeral fractures in children who are not yet walking compared with children who are ambulatory,^{15–18} and the percentage of fractures caused by abuse declines sharply after the child begins to walk.^{9,19,20}

Fracture Specificity for Abuse

Fractures With High Specificity for Abuse

As shown in Table 1, certain fractures have high specificity for or strong association with child abuse, particularly in infants, whereas others may have less specificity.²¹ Rib fractures in infants, especially those situated posteromedially, and the classic metaphyseal lesions of long bones, have high specificity for child abuse. Fractures of the scapula, spinous process, and sternum also have high specificity for abuse but are uncommon.

Rib fractures are highly suggestive of child abuse. Most abusive rib fractures result from anterior-posterior compression of the chest. For this reason, rib fractures are frequently found in infants who are held around the chest, squeezed, and shaken. Rib fractures have high probability of being caused by abuse.^{15,17,21} The positive predictive value of rib fractures for child abuse in children younger than 3 years was 95% in one retrospective study.²² Other less common causes of rib fractures in infants include significant trauma sustained during childbirth or a motor vehicle crash as well as minor trauma

in infants who have increased bone fragility.^{23–25}

Cardiopulmonary resuscitation (CPR) has been proposed as a cause of rib fractures, but conventional CPR with 2 fingers of 1 hand rarely causes fractures in children.^{26,27} Recent recommendations that CPR be performed using 2 hands encircling the rib cage have raised concerns that this technique might cause rib fractures. An analysis of infants who were discovered during autopsy to have rib fractures and had received 2-handed chest compressions antemortem suggested that 2-handed CPR is associated with anterior-lateral rib fractures of the third to sixth ribs.²⁸ In this small study, no posterior rib fractures were observed. The fractures in these infants were always multiple, uniformly involved the fourth rib, and were sometimes bilateral. Additional research is needed to examine the relationship between the 2-handed CPR technique and rib fractures.

Classic metaphyseal lesions (CMLs) also have high specificity for child abuse when they occur during the first year of life.^{21,29} CMLs are the most common long bone fracture found in infants who die with evidence of inflicted injury.³⁰ CMLs are planar fractures through the primary spongiosa of the metaphysis. These fractures are caused when torsional and tractional shearing strains are applied across the metaphysis, as may occur with vigorous pulling or twisting of an infant's extremity.³¹ Fractures resembling CMLs radiographically have been reported after breech delivery³² and as a result of treatment of clubfoot.³³

Depending on the projection of the radiograph, CMLs can have the appearance of a corner or a bucket-handle fracture. Acute injuries can

TABLE 1 Specificity of radiologic findings in infants and toddlers¹⁹

High specificity ^a
CMLs
Rib fractures, especially posteromedial
Scapular fractures
Spinous process fractures
Sternal fractures
Moderate specificity
Multiple fractures, especially bilateral
Fractures of different ages
Epiphyseal separations
Vertebral body fractures and subluxations
Digital fractures
Complex skull fractures
Common, but low specificity
Subperiosteal new bone formation
Clavicular fractures
Long-bone shaft fractures
Linear skull fractures

^a Highest specificity applies in infants.

be difficult to visualize radiographically. CMLs commonly heal without subperiosteal new bone formation or marginal sclerosis. They can heal quickly and be undetectable on plain radiographs in 4 to 8 weeks.³¹

Fractures With Moderate Specificity for Abuse

Although many children who have been abused will have only a single fracture,³⁴ the presence of multiple fractures, fractures of different ages and/or stages of healing, and complex skull fractures have moderate specificity for physical abuse. In addition, epiphyseal separations, vertebral body fractures, and digital fractures have moderate specificity for abuse. The presence of multiple fractures or fractures of different ages can be signs of bone fragility but should also evoke consideration of child abuse. Besides the predictive value of the particular pattern of fractures, many other factors, such as the history and the child's age, must be considered when determining whether the injury was inflicted.

Common Fractures With Low Specificity for Child Abuse

Long bone fractures (other than CMLs), linear skull fractures, clavicle fractures, and isolated findings of subperiosteal new bone formation have low specificity for child abuse. In contrast, the single long bone diaphyseal fracture is the most common fracture pattern identified in abused children.^{1,13,34}

An understanding of the extent and type of load that is necessary to cause a particular long bone fracture can help to determine whether a specific fracture is consistent with the injury described by the caregiver.^{35,36} Transverse fractures of the long bones are caused by the application of a bending load in a direction that is perpendicular

to the bone, whereas spiral fractures are caused by torsion or twisting of a long bone along its long axis. Oblique fractures are caused by a combination of bending and torsion loads.³⁷ Torus or buckle fractures are the result of compression from axial loading along the length of the bone. Although earlier studies suggested that spiral fractures should always raise suspicion for child abuse,¹² more recent studies do not show that any particular fracture pattern can distinguish between abuse and nonabuse with absolute certainty.^{16,38}

Falls are common in childhood.³⁹ Short falls can cause fractures, but they rarely result in additional significant injury (eg, neurologic injury).^{11,40–42} In a retrospective study of short falls, parents reported that 40% of the children before 2 years of age had suffered at least 1 fall from a height of between 6 inches and 4 feet. Approximately one-quarter of these children suffered an injury; bruises were the most common injury observed.⁴³

The femur, humerus, and tibia are the most common long bones to be injured by child abuse.^{1,34} Femoral fractures in the nonambulatory child are more likely caused by child abuse, whereas these fractures in ambulatory children are most commonly noninflicted.^{10,16,43–45}

Certain femur fractures may occur as a result of a noninflicted injury in young children. Several studies have demonstrated that a short fall to the knee may produce a torus or impacted transverse fracture of the distal femoral metaphysis.^{46,47} Oblique distal femur metaphyseal fractures have been reported in children playing in a stationary activity center, such as an Exersaucer (Evenflo, Picqua, OH).⁴⁸

In both ambulatory and nonambulatory children, under some circumstances, falls on a stairway can cause a spiral femoral fracture. For example, a fall

down several steps and landing with 1 leg folded or twisted underneath a child can lead to excessive torsional loading of the femur and a spiral fracture.⁴⁶ In ambulatory children, noninflicted femoral fractures have been described in children who fell while running or who fell and landed in a split-leg position.⁴³

A fracture of the humeral shaft in a child younger than 18 months has a high likelihood of having been caused by abuse.^{15,49,50} In contrast, supracondylar fractures in ambulatory children are usually noninflicted injuries resulting from short falls.¹⁵

Physicians should also be aware of a particular mechanism reported to produce a noninflicted spiral-oblique fracture of the humerus in 1 case report.⁵¹ When the young infant was rolled from the prone position to the supine while the child's arm is extended, the torsion and stress placed on the extended arm appeared to cause a spiral-oblique fracture of the midshaft of the humerus.

Linear skull fractures of the parietal bone are the most common skull fracture among young children, usually children younger than 1 year.¹³ A short fall from several feet onto a hard surface can cause a linear, nondiastatic skull fracture.^{19,52} The majority of linear skull fractures are not inflicted.⁵³ By contrast, complex or bilateral skull fractures are typical of nonaccidental trauma.

Syndromes, Metabolic Disorders, Systemic Disease

Preexisting medical conditions and bone disease may make a child's bones more vulnerable to fracture. Some conditions may manifest skeletal changes, such as metaphyseal irregularity and subperiosteal new bone formation. These entities should be considered in the differential diagnosis of childhood fractures.

Osteogenesis Imperfecta

Osteogenesis imperfecta (OI) is a heterogeneous family of diseases, usually caused by heterozygous mutations of the genes *COL1A1* and *COL1A2*,⁵⁴ but mutations in these and other genes can cause autosomal recessive forms of OI. The *COL1A1* and *COL1A2* genes encode the chains of type I collagen, which forms the structural framework of bone. Although it is a genetic disorder, many children have de novo mutations or autosomal-recessive disease and no family history of bone fragility. In addition, the presentation of the disease within affected members of the same family can be quite variable. Phenotypic expression of the disease depends on the nature of the mutation, its relative abundance attributable to mosaicism, and its expression in target tissues.⁵⁵ Some types of OI involve reduced production of collagen, and the symptoms resolve or lessen after puberty.⁵⁶ Table 2 lists the various signs and symptoms that can be present in a case of OI.

The diagnosis of OI is often suggested by a family history of fractures, short stature, blue sclera, poor dentition, and radiographic evidence of low bone density or osteopenia. The fractures are most commonly transverse in nature, occurring in the shafts of the

long bones. It is unusual to have multiple long bone fractures or rib fractures, particularly in infancy, without other clinical and radiographic evidence of OI.^{57,58}

OI has been misdiagnosed as child abuse.⁵⁹ On the other hand, OI is often suggested as the cause of fractures in children who have been abused. If fractures continue to occur when a child is placed in a protective environment, a more thorough evaluation for an underlying bone disease is needed. Child abuse is more common than OI,⁶⁰ and children with OI and other metabolic or genetic conditions may also be abused.^{61,62}

Preterm Birth

Preterm infants have decreased bone mineralization at birth, but after the first year of life, bone density normalizes.^{63,64} Osteopenia of prematurity has been well described as a complication in low birth weight infants.⁶⁵ Infants born at less than 28 weeks' gestation or who weigh less than 1500 g at birth are particularly vulnerable. Osteopenia of prematurity is multifactorial. Infants are also at risk if they receive prolonged (for 4 or more weeks) total parenteral nutrition, have bronchopulmonary dysplasia, and/or have received a prolonged course of diuretics or steroids.⁶⁶ Osteopenia commonly presents between 6 and 12 weeks of life. Osteopenia of prematurity can be ameliorated if infants are monitored closely and receive the nutritional and mineral supplementation initiated in the NICU.

Fractures associated with osteopenia of prematurity usually occur in the first year of life.⁶⁷ Rib fractures are typically encountered incidentally, whereas long bone fractures commonly present with swelling of the extremity. Osteopenia of prematurity can be associated with rickets, and in such cases, metaphyseal irregularities may be present.

Although osteopenia of prematurity may make the infant more vulnerable to fracture, preterm infants are also at an increased risk of abuse.⁶⁸

Vitamin D Deficiency Rickets

Suboptimal vitamin D concentrations and rickets have been proposed as causes of fractures in infants.⁶⁹ Vitamin D insufficiency in otherwise healthy infants and toddlers is common. Approximately 40% of infants and toddlers aged 8 to 24 months in an urban clinic had laboratory evidence of vitamin D insufficiency (serum concentrations of 25-hydroxyvitamin D of ≤ 30 ng/mL).⁷⁰ Prolonged breastfeeding without vitamin D supplementation was a critical factor that placed these infants at risk, although increased skin pigmentation and/or lack of sunlight exposure may also have contributed. Rickets is characterized by demineralization, loss of the zone of provisional calcification, widening and irregularity of the physis, and fraying and cupping of the metaphysis.⁷¹ Despite the high prevalence of vitamin D insufficiency in infants and toddlers, rickets is uncommon.⁷²

The claim that vitamin D deficiency or insufficiency causes skeletal lesions that lead to the incorrect diagnosis of child abuse in infants is not supported in the literature. A systematic clinical, laboratory, and radiologic assessment should exclude that possibility.^{73–75} Schilling et al found no difference in serum concentrations of 25-hydroxyvitamin D in young children with fractures suspicious for abuse and noninflicted fractures.⁷⁶ Vitamin D insufficiency was not associated with multiple fractures, in particular rib fractures or CMLs, the high specificity indicators of abuse. Perez-Rossello et al studied radiographs of 40 healthy older infants and toddlers with

TABLE 2 Characteristics of Osteogenesis Imperfecta

Fragile bones with few, some, or many of the following findings:
Poor linear growth
Macrocephaly
Triangular-shaped face
Blue sclerae
Hearing impairment as a result of otosclerosis
Hypoplastic, translucent, carious, late-erupting, or discolored teeth
Easy bruisability
Inguinal and/or umbilical hernias
Limb deformities
Hyperextensible joints
Scoliosis and/or kyphosis
Wormian bones of the skull
Demineralized bones

vitamin D insufficiency and deficiency and concluded that radiographic rachitic changes were uncommon and very mild. In this population, the reported fracture prevalence was zero.⁷²

In a study of 45 young children with radiographic evidence of rickets, investigators found that fractures occurred only in those infants and toddlers who were mobile.⁷⁷ Fractures were seen in 17.5% of the children, and these children were 8 to 19 months of age. The fractures involved long bones, anterior-lateral and lateral ribs, and metatarsal and metaphyseal regions. The metaphyseal fractures occurred closer to the diaphysis in the background of florid metaphyseal rachitic changes and did not resemble the juxtaphyseal corner or bucket handle pattern of the CML. In infant fatalities in which abuse is suspected, rachitic changes appear to be rare histologically.⁷⁸

Osteomyelitis

Osteomyelitis in infants can present as multiple metaphyseal irregularities potentially resembling CMLs.⁷⁹ Typically, the lesions become progressively lytic and sclerotic with substantial subperiosteal new bone formation. Other signs of infection are often present, such as fever, increased erythrocyte sedimentation rate, elevated C-reactive protein concentration, and elevated white blood cell count.

Fractures Secondary to Demineralization From Disuse

Any child with a severe disability that limits or prevents ambulation can be at risk for fractures secondary to disuse demineralization, even with normal handling.^{80,81} The fractures are usually diaphyseal rather than CMLs. Often, these fractures occur during physical therapy and range-of-motion exercises. It can be difficult to distinguish between

inflicted and noninflicted fractures occurring in these children. At the same time, children with disabilities are at an increased risk of being maltreated.^{82–84} When multiple or recurrent fractures occur in a disabled child, a trial change in caregivers may be indicated to determine whether the fractures can be prevented. This is an extreme intervention and should be reserved for unusual circumstances.⁶³

Scurvy

Scurvy is caused by insufficient intake of vitamin C, which is important for the synthesis of collagen. Although rare today because formula, human milk, fruits, and vegetables contain vitamin C, scurvy may develop in older infants and children given exclusively cow milk without vitamin supplementation and in children who eat no foods containing vitamin C.^{85–87} Although scurvy can result in metaphyseal changes similar to those seen with child abuse, other characteristic bone changes, including osteopenia, increased sclerosis of the zones of provisional calcification, dense epiphyseal rings, and extensive calcification of subperiosteal and soft tissue hemorrhages, will point to the diagnosis of scurvy.

Copper Deficiency

Copper plays a role in cartilage formation. Copper deficiency is a rare condition that may be complicated by bone fractures. Preterm infants are born with lower stores of copper than term infants, because copper is accumulated at a faster rate during the last trimester.⁸⁸ Copper insufficiency may be observed in children with severe nutritional disorders, for example, liver failure or short gut syndrome.⁸⁹ This deficiency is not likely to be observed in full-term children younger than 6 months of age or preterm infants younger than 2.5

months of age, because fetal copper stores are sufficient for this length of time. In addition, human milk and formula contain sufficient copper to prevent deficiency. Psychomotor retardation, hypotonia, hypopigmentation, pallor, and a sideroblastic anemia are some of the characteristic findings of copper deficiency in infants. Radiologic changes that should lead to further evaluation for possible deficiency include cupping and fraying of the metaphyses, sickle-shaped metaphyseal spurs, significant demineralization, and subperiosteal new bone formation.

Menkes Disease

Menkes disease, also known as Menkes kinky hair syndrome, is a rare congenital defect of copper metabolism.⁹⁰ Menkes disease is an X-linked recessive condition and occurs only in boys. Although it has many of the features of dietary copper deficiency, anemia is not associated with Menkes disease. Metaphyseal fragmentation and subperiosteal new bone formation may be observed on radiographs, and the findings may be difficult to distinguish from fractures caused by abuse.⁹¹ Other signs of Menkes disease include sparse, kinky hair, calvarial wormian bones, anterior rib flaring, failure to thrive, and developmental delay. A characteristic finding is tortuous cerebral vessels. Intracranial hemorrhage can occur in Menkes disease but has not been reported in infants with copper deficiency.

Systemic Disease

Chronic renal disease affects bone metabolism because children with chronic renal disease may develop a metabolic acidosis that interferes with vitamin D metabolism. Chronic renal disease can cause renal osteodystrophy resulting in the same radiographic changes as nutritional

rickets. Because chronic liver disease (eg, biliary atresia) interferes with vitamin D metabolism, such children may be at an increased risk of fractures. Fanconi syndrome, hypophosphatasia, hypophosphatemic (vitamin D resistant) rickets, hyperparathyroidism, and renal tubular acidosis also cause clinical variants of rickets.

Temporary Brittle Bone Disease Hypothesis

Physicians should be aware of alternative diagnoses that are unsupported by research but are sometimes suggested when an infant has unexplained fractures. In 1993, Paterson proposed that some infants may be born with bones that are temporarily more fragile or vulnerable to fracture in the context of normal handling, which he called “temporary brittle bone disease.”⁹² Paterson suggested that some trace element deficiency, such as copper or a transient collagen immaturity, caused the disease but provided no scientific data that confirmed his hypotheses and offered no specific test that confirmed temporary brittle bone disease.⁶¹ Subsequent studies did not support his hypotheses, and his case analysis has been refuted.^{57,93–95}

Miller hypothesized that temporary brittle bone disease is a result of fetal immobilization or intrauterine confinement that leads to transient bone loss or osteopenia.^{96,97} In support of his hypothesis, he reported that 95% of 21 infants with multiple unexplained fractures had decreased fetal movements, according to their mothers.^{97,98} Although he used bone densitometry in each patient as a basis for his conclusions, none of the patients had had bone densitometry performed at the time of the fracture. The testing was performed 8 to 21 weeks later, and no infants were tested before 5 months of age. In addition, bone densitometry standards have not been established

for infants. He relied on the mother's history of decreased fetal movements and provided no independent measurements of those movements. Palacios and Rodríguez found no evidence that oligohydramnios affects bone mass of the fetus, probably because fetal movement is only restricted in the last trimester of pregnancy by oligohydramnios and because the mechanical loading on the bones stimulating bone formation is conserved.⁹⁹

Medical Evaluation

History of Present Illness

It is essential to obtain a detailed history to determine how an injury occurred. If an injury in a nonverbal child was witnessed, the caregiver should be able to provide details about the child's activity and position before an injury and the child's final position and location after the injury occurred.⁴⁶ Verbal children with concerning fractures should be interviewed apart from caregivers and ideally by a professional who is skilled in forensic interviewing.

A comparison of the histories provided by caregivers of children with non-inflicted femoral fractures and by caregivers of children whose injuries were caused by abuse is instructive. When an injury was caused by abuse, the caregiver provided either no history of an injury or related a history of a low-energy event. By contrast, 29% of the caregivers of children with non-inflicted injuries provided some high-energy explanation, such as a motor vehicle collision or that the child fell from a height.¹⁶ Most of the low-energy mechanisms provided for the noninflicted injuries involved falls including stair falls and siblings landing on the femur during play.^{16,46}

The child's response to the event may also provide important clues about the etiology. The majority of children with long bone fractures will have

some swelling, pain, or other signs, such as decreased use of the extremity, suggesting a fracture.^{100,101} Some children, however, will have minimal external signs of injury.¹⁰² The absence of any history of injury, a vague description of the event, a delay in seeking care, the absence of an explanation for an injury particularly in a nonambulatory child, or an inconsistent explanation should increase the physician's concern that an injury was caused by child abuse (see Table 3).^{13,16}

Past Medical History

The past medical history is important and should include details about the mother's pregnancy. If the child was born preterm, the infant's bone mineral content may be reduced, and the infant may be at risk for fracture. A history of total parental nutrition, hepatobiliary disease, diuretic therapy, hypercalciuria, or corticosteroids may make the bones of a low birth weight infant even more vulnerable to fracture. In addition, chronic diseases, such as renal insufficiency or metabolic acidosis, malabsorption, cerebral palsy or other neuromuscular disorders, genetic diseases that affect skeletal development, or any illness that limits mobility, may affect bone strength. A thorough dietary history and history of medications that can

TABLE 3 When Is a Fracture Suspicious for Child Abuse?

- No history of injury
- History of injury not plausible—mechanism described not consistent with the type of fracture, the energy load needed to cause the fracture, or the severity of the injury
- Inconsistent histories or changing histories provided by caregiver
- Fracture in a nonambulatory child
- Fracture of high specificity for child abuse (eg, rib fractures)
- Multiple fractures
- Fractures of different ages
- Other injuries suspicious for child abuse
- Delay in seeking care for an injury

predispose to fractures are important. The physician should inquire about previous injuries including bruises and determine the child's developmental abilities, because children who are not yet mobile are much more likely to have fractures caused by abuse.

Family History

A family history of multiple fractures, early-onset hearing loss, abnormally developed dentition, blue sclera, and short stature should suggest the possibility of OI.

Social History

The physician should obtain a complete psychosocial history, including asking who lives in the home and who has provided care for the child. The history should inquire about intimate partner violence, substance abuse including drugs and alcohol, mental illness, and previous involvement with child protective services and/or law enforcement.

Physical Examination

The child should have a comprehensive physical examination, and the growth chart should be carefully reviewed. Abnormal weight may suggest neglect or endocrine or metabolic disorders. Any signs or symptoms of fractures, such as swelling, limitation of motion, and point tenderness should be documented. The physician should do a complete skin examination to look for bruises and other skin findings because bruises are the most common injury caused by child abuse. The majority of children with fractures do not have bruising associated with the fracture; the presence or absence of such bruising does not help to determine which fractures are caused by child abuse.^{103,104} Bruising in a child who is not yet cruising or bruising in unusual locations, such as the ears,

neck, or trunk should raise suspicion for child abuse.^{105,106} The child should be examined for other injuries caused by child abuse, in addition to signs of other medical conditions associated with bone fragility. Blue sclerae are seen in certain types of OI. Sparse, kinky hair is associated with Menkes disease. Dentinogenesis imperfecta is occasionally identified in older children with OI.

Laboratory Evaluation

The clinical evaluation should guide the laboratory evaluation. In children with fractures suspicious for abuse, serum calcium, phosphorus, and alkaline phosphatase should be reviewed, although alkaline phosphatase may be elevated with healing fractures. The physician should consider checking serum concentrations of parathyroid hormone and 25-hydroxyvitamin D, as well as urinary calcium excretion (eg, random urinary calcium/creatinine ratio) in all young children with fractures concerning for abuse, but these levels should certainly be assessed if there is radiographic evidence of osteopenia or metabolic bone disease. Screening for abdominal trauma with liver function studies as well as amylase and lipase concentration should be performed when severe or multiple injuries are identified. A urinalysis should be performed to screen for occult blood. Serum copper, vitamin C, and ceruloplasmin concentrations should be considered if the child is at risk for scurvy or copper deficiency and has radiographic findings that include metaphyseal abnormalities.

If OI is suspected, sequence analysis of the *COL1A1* and *COL1A2* genes that are associated with 90% of cases of OI as well as other genes associated with less common autosomal-recessive forms of OI may be more sensitive than biochemical tests of

type I collagen and may identify the mutation to guide testing of other family members.¹⁰⁷ Some of the less common forms of OI are OI types IIB and VII, *CRTAP*; OI type VI, *FKBP10*; OI type VIII, *LEPRE1*; OI type IX, *PP1B*; OI type X, *SERPINH1*; OI type XI, *SP7*; OI type XII, *SERPINF1*; and OI type XIII, *BMP1*. DNA sequencing can be performed using genomic DNA isolated from peripheral blood mononuclear cells or even saliva, whereas the biochemical analysis of type I collagen requires a skin biopsy. Doing both DNA analysis and skin biopsy is not indicated in most cases. Consultation with a pediatric geneticist may be helpful in deciding which children to test and which test to order.¹⁰⁸

Imaging Approach

Children younger than 2 years with fractures suspicious for child abuse should have a radiographic skeletal survey to look for other bone injuries or osseous abnormalities.¹⁰⁹ Additional fractures are identified in approximately 10% of skeletal surveys, with higher yields in infants.¹¹⁰ Skeletal surveys may be appropriate in some children between ages 2 and 5 years, depending on the clinical suspicion of abuse. If specific clinical findings indicate an injury at a particular site, imaging of that area should be obtained regardless of the child's age.

The American College of Radiology has developed specific practice guidelines for skeletal surveys in children.¹¹¹ Twenty-one images are obtained, including frontal images of the appendicular skeleton, frontal and lateral views of the axial skeleton, and oblique views of the chest. Oblique views of the chest have been shown to increase the sensitivity, specificity, and accuracy of the identification of rib fractures.¹¹² A full 4 skull series should be obtained if there are concerns of

head injury. Computed tomography (CT) 3-dimensional models are valuable adjuncts to the radiographs and have the potential to replace the skull series.¹¹³ This has not been studied systematically in this context, however. Because lateral views of the extremities increase yield, some authors suggest that these views be included in the imaging protocol.¹¹⁴ Fractures may be missed if the guidelines are not followed or if the images are of poor quality.¹¹⁵ A repeat skeletal survey should be performed approximately 2 to 3 weeks after the initial skeletal survey if child abuse is strongly suspected.^{109,116} The follow-up examination may identify fractures not seen on the initial skeletal survey, can clarify uncertain findings identified by the initial skeletal survey, and improves both sensitivity and specificity of the skeletal survey.^{116,117} In one study, 13 of 19 fractures found on the follow-up examination were not seen on the initial series.¹¹⁶ The number of images on the follow-up examination may be limited to 15 views by omitting the views of the skull, pelvis, and lateral spine.¹¹⁸

Radiography may assist in assessing the approximate time when an injury occurred because long bone fractures heal following a particular sequence.¹¹⁹ If the healing pattern is not consistent with the explanation provided, the accuracy of the explanation should be questioned.

Bone scintigraphy may be used to complement the skeletal survey but should not be the sole method of identifying fractures in infants. Although it has high overall sensitivity, it lacks specificity for fracture detection and may fail to identify CMLs and skull fractures.^{109,119,120} Scintigraphy does have high sensitivity for identifying rib fractures, which can be difficult to detect before healing. In toddlers and older children, the use of bone scintigraphy or skeletal survey depends on

the specific clinical indicators of abuse.¹⁰⁹

Because brain injuries are often occult, head imaging should be considered for any child younger than 1 year with a fracture suspicious for abuse.¹²¹ Imaging studies may help clarify whether the child has been abused, provide further support for a diagnosis of child abuse, and identify other injuries that require treatment. Additional imaging may be needed if the child has signs or symptoms of chest, abdominal, or neck injury.

Chest CT can identify rib fractures that are not seen on chest radiographs.¹²² CT is particularly useful in detecting anterior rib fractures and rib fractures at all stages of healing—early subacute, subacute, and old fractures. Although CT may be more sensitive in identifying these injuries, a chest CT exposes the child to significantly more radiation than chest radiography. Every effort should be made to reduce children's exposure to radiation while at the same time considering the risk to the child if abuse is not identified.¹²³ Therefore, selective application of this technique in certain clinical settings is appropriate.

Other modalities may become available in the future that will provide more accurate identification of skeletal injuries. Whole-body short tau inverse recovery imaging, a magnetic resonance imaging (MRI) technique, may identify rib fractures not recognized on the radiographic skeletal survey.¹²⁴ In a study of 21 infants with suspected abuse, whole-body MRI at 1.5-Tesla was insensitive in the detection of CMLs and rib fractures. In some cases, whole-body MRI identified soft tissue edema and joint effusions that led to the identification of skeletal injuries with additional radiographs.¹²⁵ Bone scintigraphy with ¹⁸F-sodium fluoride positron emission tomography (¹⁸F-NaF PET) bone scan may be useful in cases

of equivocal or negative skeletal surveys when there is high clinical suspicion of abuse. If available, a ¹⁸F-NaF positron emission tomography bone scan has better contrast and spatial resolution than ^{99m}Tc-labeled methylene diphosphonate.¹²⁰

Although bone densitometry by dual-energy x-ray absorptiometry is useful to predict bone fragility and fracture risk in older adults, interpretation of bone densitometry in children and adolescents is more problematic.¹²⁶ In adults, bone densitometry is interpreted using T scores, which describe the number of SDs above or below the average peak bone mass for a gender- and race-adjusted reference group of normal subjects. Because peak bone mass is not achieved until approximately 30 years of age, in children, z scores must be used to express bone density, because z scores express the child's bone mineral density as a function of SDs above or below the average for an age- and gender-matched norm control population.¹²⁷ In addition, because bone size influences dual-energy x-ray absorptiometry, z scores must also be adjusted for height z scores.¹²⁸ The International Society for Clinical Densitometry recommends that the diagnosis of osteoporosis in childhood should not be made on the basis of low bone mass alone but should also include a clinically significant history of low-impact fracture. The recommendations currently apply to children 5 years and older, although reference data are available for children as young as 3 years.^{129,130} Unfortunately, there are limited reference data for the young, nonverbal child who is most at risk for suffering fractures caused by child abuse.

Evaluation of Siblings

Siblings, especially twins, and other young household members of children who have been physically abused

should be evaluated for maltreatment.¹³¹ In a study of 795 siblings in 400 households of a child who had been abused or neglected, all siblings in 37% of households and some siblings in 20% of households had suffered some form of maltreatment.¹³² In this study, which included all manifestations of maltreatment, siblings were found to be more at risk for maltreatment if the index child suffered moderate or severe maltreatment. In addition to a careful evaluation, imaging should be considered for any siblings younger than 2 years, especially if there are signs of abuse.

DIAGNOSIS

When evaluating a child with a fracture, physicians must take a careful history of any injury event and then determine whether the mechanism described and the severity and timing are consistent with the injury identified (see Table 3).¹³³ They must consider and evaluate for possible diagnoses in addition to other signs or symptoms of child abuse. A careful evaluation for other injuries is important because the presence of additional injuries that are associated with child abuse increases the likelihood that a particular fracture was inflicted.^{16,43} It is important to remember that even if a child has an underlying disorder or disability that could increase the likelihood of a fracture, the child may also have been abused because children with disabilities and other special health care needs are at increased risk of child abuse.^{83,84} Physicians should keep an open mind to the possibility of abuse and remember that child abuse occurs in all socioeconomic

groups and across all racial and ethnic groups. Many of these diagnoses are complex. If a physician is uncertain about how to evaluate an injury or if they should suspect a fracture was caused by child abuse, they should consult a child abuse pediatrician or multidisciplinary child abuse team to assist in the evaluation, particularly if the child is nonambulatory or younger than 1 year of age.¹³⁴ In certain circumstances, the physician will need to consult an orthopedist, endocrinologist, geneticist, or other subspecialists.

All US states, commonwealths, and territories have mandatory reporting requirements for physicians and other health care providers when child abuse is suspected. Physicians should be aware of and comply with the reporting requirements of their state. Typically, the standard for making a report is when the reporter “suspects” or “has reason to believe” that a child has been abused or neglected. Sometimes determining whether that “reasonable belief” or “reasonable suspicion” standard has been met can be nuanced and complex. The physician should keep in mind that incontrovertible proof of abuse or neglect is not required by state statutes, and there may be cases in which it is reasonable to consult with a child abuse pediatrician about whether a report should be made.

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Fluoride Use in Caries Prevention in the Primary Care Setting

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- *Clinical Report*

CLINICAL REPORT

Fluoride Use in Caries Prevention in the Primary Care Setting

abstract

FREE

Dental caries remains the most common chronic disease of childhood in the United States. Caries is a largely preventable condition, and fluoride has proven effectiveness in the prevention of caries. The goals of this clinical report are to clarify the use of available fluoride modalities for caries prevention in the primary care setting and to assist pediatricians in using fluoride to achieve maximum protection against dental caries while minimizing the likelihood of enamel fluorosis. *Pediatrics* 2014;134:626–633

Dental caries (ie, tooth decay) is an infectious disease in which acid produced by bacteria dissolves tooth enamel. If not halted, this process will continue through the tooth and into the pulp, resulting in pain and tooth loss. This activity can further progress to local infections (ie, dental alveolar abscess or facial cellulitis), systemic infection, and, in rare cases, death. Dental caries in the United States is responsible for many of the 51 million school hours lost per year as a result of dental-related illness, which translates into lost work hours for the parent or adult caregiver.¹ Early childhood caries is the single greatest risk factor for caries in the permanent dentition. Good oral health is a necessary part of overall health, and recent studies have demonstrated the adverse effects of poor oral health on multiple other chronic conditions, including diabetes control.² Therefore, the failure to prevent caries has health, educational, and financial consequences at both the individual and societal level.

Dental caries is the most common chronic disease of childhood,¹ with 59% of 12- to 19-year-olds having at least 1 documented cavity.³ Caries is the “silent epidemic” that disproportionately affects poor, young, and minority populations.¹ The prevalence of dental caries in very young children increased during the period between the last 2 national surveys, despite improvements for older children.⁴ Because many children do not receive dental care at young ages, and risk factors for dental caries are influenced by parenting practices, pediatricians have a unique opportunity to participate in the primary prevention of dental caries. Studies show that simple home and primary care setting prevention measures would save health care dollars.⁵

Development of dental caries requires 4 components: teeth, bacteria, carbohydrate exposure, and time. Once teeth emerge, they may become colonized with cariogenic bacteria. The bacteria metabolize carbohydrates

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KEY WORDS

enamel fluorosis, fluoride, fluoride varnish, formula mixing, systemic fluoride supplements, toothpaste, water fluoridation

ABBREVIATIONS

AAP—American Academy of Pediatrics

ADA—American Dental Association

CDC—Centers for Disease Control and Prevention

EPA—Environmental Protection Agency

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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and create acid as a byproduct. The acid dissolves the mineral content of enamel (demineralization) and, over time with repeated acid attacks, the enamel surface collapses and results in a cavity in the tooth. Protective factors that help to remineralize enamel include exposing the teeth to fluoride, limiting the frequency of carbohydrate consumption, choosing less cariogenic foods, practicing good oral hygiene, receiving regular dental care, and delaying bacterial colonization. If carious lesions are identified early, the process can be halted or reversed by modifying the patient's individual risk and protective factors. Certain American Academy of Pediatrics (AAP) publications (*Oral Health Risk Assessment Timing and Establishment of the Dental Home*⁶ and *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*⁷) discuss these concepts in greater depth and provide targeted preventive anticipatory guidance. The Medical Expenditure Panel Survey demonstrated that 89% of infants and 1-year-olds have office-based physician visits annually, compared with only 1.5% who have dental visits.⁸ For primary prevention to be effective, it is imperative that pediatricians be knowledgeable about the process of dental caries, prevention of the disease, and available interventions, including fluoride.

Fluoride is available from many sources and is divided into 3 major categories: tap water (and foods and beverages processed with fluoridated water), home administered, and professionally applied. There has been substantial public and professional debate about fluoride, and myriad information is available, often with confusing or conflicting messages. The widespread decline in dental caries in many developed countries, including the United States, has been largely attributable to the use of fluoride. Fluoride has 3 main mechanisms of action: (1) it promotes enamel remineralization; (2) it

reduces enamel demineralization; and (3) it inhibits bacterial metabolism and acid production.⁹ The mechanisms of fluoride are both topical and systemic, but the topical effect is the most important, especially over the life span.¹⁰

RISK OF FLUOROSIS

The only scientifically proven risk of fluoride use is the development of fluorosis, which may occur with fluoride ingestion during tooth and bone development. Fluorosis of permanent teeth occurs when fluoride of sufficient quantity for a sufficient period of time is ingested during the time that tooth enamel is being mineralized. Fluorosis is the result of subsurface hypomineralization and porosity between the developing enamel rods.¹¹ This risk exists in children younger than 8 years, and the most susceptible period for permanent maxillary incisor fluorosis is between 15 and 30 months of age.^{12–14} The risk of fluorosis is influenced by both the dose and frequency of exposure to fluoride during tooth development.¹⁵ Recent evidence also suggests that individual susceptibility or resistance to fluorosis includes a genetic component.¹⁶

After 8 years of age, there is no further risk of fluorosis (except for the third molars) because the permanent tooth enamel is fully mineralized. The vast majority of enamel fluorosis is mild or very mild and characterized by small

white striations or opaque areas that are not readily noticeable to the casual observer. Although this type of fluorosis is of no clinical consequence, enamel fluorosis has been increasing in frequency over the last 2 decades to a rate of approximately 41% among adolescents because fluoride sources are more widely available in varied forms.¹⁷ Moderate and severe forms of enamel fluorosis are uncommon in the United States but have both an aesthetic concern and potentially a structural concern, with pitting, brittle incisal edges, and weakened groove anatomy in the permanent 6-year molars.

In 2001, the AAP endorsed the guidelines from the Centers for Disease Control and Prevention (CDC), "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States."¹⁵ Dental and governmental organizations (American Dental Association [ADA], American Academy of Pediatric Dentistry, the Department of Health and Human Services, and the CDC) have more recently published guidelines on the use of fluoride, but current AAP publications do not reflect these newer evidence-based guidelines. Table 1 provides a simple explanation of fluoride use for patients at low and high risk of caries.

The present report has 2 goals: (1) to assist pediatricians in using fluoride to achieve maximum protection against

TABLE 1 Summary of Fluoride Modalities for Low- and High-Risk Patients

Fluoride Modality	Low Caries Risk	High Caries Risk
Toothpaste	Starting at tooth emergence (smear of paste until age 3 y, then pea-sized)	Starting at tooth emergence (smear of paste until age 3 y, then pea-sized)
Fluoride varnish	Every 3–6 mo starting at tooth emergence	Every 3–6 mo starting at tooth emergence
Over-the-counter mouth rinse	Not applicable	Starting at age 6 y if the child can reliably swish and spit
Community water fluoridation	Yes	Yes
Dietary fluoride supplements	Yes, if drinking water supply is not fluoridated	Yes, if drinking water supply is not fluoridated

dental caries while minimizing the likelihood of enamel fluorosis; and (2) to clarify the advice that should be given by pediatricians regarding fluoride in the primary care setting.

CURRENT INFORMATION REGARDING FLUORIDE USE IN CARIES PREVENTION

The following information aims to assist pediatricians in achieving maximum protection against dental caries for their patients while minimizing the likelihood of enamel fluorosis. Sources of ingested fluoride include drinking water, infant formula, fluoride toothpaste, prescription fluoride supplements, fluoride mouth rinses, professionally applied topical fluoride, and some foods and beverages.¹⁸

Fluoride Toothpaste

Fluoride toothpaste has consistently been proven to provide a caries-preventive effect for individuals of all ages.^{15,19} In the United States, the fluoride concentration of over-the-counter toothpaste ranges from 1000 to 1100 ppm. In some other countries, toothpastes containing 1500 ppm of fluoride are available. A 1-inch (1-g) strip of toothpaste translates to 1 or 1.5 mg of fluoride, respectively. A pea-sized amount of toothpaste is approximately one-quarter of an inch. Therefore, a pea-sized amount of toothpaste containing 1000/1100 ppm of fluoride would have approximately 0.25 mg of fluoride, and the same amount of toothpaste containing 1500 ppm of fluoride would have approximately 0.38 mg of fluoride. Most fluoride toothpaste in the United States contains sodium fluoride, sodium monofluorophosphate, or stannous fluoride as the active ingredient. Parents should supervise children younger than 8 years to ensure the proper amount of toothpaste and effective brushing technique. Children younger than 6 years are more likely to ingest some or all of the toothpaste

used. Ingestion of excessive amounts of fluoride can increase the risk of fluorosis. This excess can be minimized by limiting the amount of toothpaste used and by storing toothpaste where young children cannot access it without parental help.

Use of fluoride toothpaste should begin with the eruption of the first tooth. When fluoride toothpaste is used for children younger than 3 years, it is recommended that the amount be limited to a smear or grain of rice size (about one-half of a pea). Once the child has turned 3 years of age, a pea-sized amount of toothpaste should be used.^{20,21} Young children should not be given water to rinse after brushing because their instinct is to swallow. Expecting without rinsing will both reduce the amount of fluoride swallowed and leave some fluoride in the saliva, where it is available for uptake by the dental plaque. Parents should be strongly advised to supervise their child's use of fluoride toothpaste to avoid overuse or ingestion.

High-concentration toothpaste (5000 ppm) is available by prescription only. The active ingredient in this toothpaste is sodium fluoride. This agent can be recommended for children 6 years and older and adolescents who are at high risk of caries and who are able to expectorate after brushing. Dentists may also prescribe this agent for adolescents who are undergoing orthodontic treatment, as they are at increased risk of caries during this time.²²

Fluoride Varnish

Fluoride varnish is a concentrated topical fluoride that is applied to the teeth by using a small brush and sets on contact with saliva. Advantages of this modality are that it is well tolerated by infants and young children, has a prolonged therapeutic effect, and can be applied by both dental and non-

dental health professionals in a variety of settings.²³ The concentration of fluoride varnish is 22 600 ppm (2.26%), and the active ingredient is sodium fluoride. The unit dose packaging from most manufacturers provides a specific measured amount (0.25 mg, providing 5 mg of fluoride ion). The application of fluoride varnish during an oral screening is of benefit to children, especially those who may have limited access to dental care. Current American Academy of Pediatric Dentistry recommendations for children at high risk of caries is that fluoride varnish be applied to their teeth every 3 to 6 months.²⁴ The 2013 ADA guideline recommends application of fluoride varnish at least every 6 months to both primary and permanent teeth in those subjects at elevated caries risk.²⁵ The US Preventive Services Task Force recently published a new recommendation that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (B recommendation).²⁶

In most states, Medicaid will pay physicians for the application of fluoride varnish. Information regarding fluoride varnish application reimbursement and which states currently provide payment can be found on the AAP Web site (<http://www2.aap.org/oralhealth/docs/OHReimbursementChart.pdf>) and the Pew Charitable Trusts Web site (<http://www.pewstates.org/research/analysis/reimbursing-physicians-for-fluoride-varnish-85899377335>). Because state regulations vary regarding whether fluoride varnish must be applied within the context of a preventive care code, this information should be determined before billing.

Indications for Use

In the primary care setting, fluoride varnish should be applied to the teeth of all infants and children at least once every 6 months and preferably every 3 months, starting when the first tooth

erupts and until establishment of a dental home.

Instructions for Use

Fluoride varnish must be applied by a dentist, dental auxiliary professional, physician, nurse, or other health care professional, depending on the practice regulations in each state. It should not be dispensed to families to apply at home. Application of fluoride varnish is most commonly performed at the time of a well-child visit. Teeth are dried with a 2-inch gauze square, and the varnish is then painted onto all surfaces of the teeth with a brush provided with the varnish. Children are instructed to eat soft foods and not to brush their teeth on the evening after the varnish application to maximize the contact time of the varnish to the tooth. The following day, they should resume brushing twice daily with fluoridated toothpaste.

Over-the-Counter Fluoride Rinse

Over-the-counter fluoride rinse provides a lower concentration of sodium fluoride than toothpaste or varnish. The concentration is most commonly 230 ppm (0.05% sodium fluoride). Expert panels on this topic have concluded that over-the-counter fluoride rinses should not be recommended for children younger than 6 years because of their limited ability to rinse and spit and the risk of swallowing higher-than-recommended levels of fluoride.²⁷ A teaspoon (5 mL) of over-the-counter fluoride rinse contains approximately 1 mg of fluoride. For children younger than 6 years, this type of rinse provides an additional, low-dose topical fluoride application that may assist in the prevention of enamel demineralization. However, the evidence for an anticaries effect is limited. The daily use of a 0.05% sodium fluoride rinse may be of benefit for children older than 6 years who are at high risk of dental caries; however, there is no additional benefit

beyond daily use of fluoridated toothpaste for children at low risk of caries.^{28,29}

Dietary Fluoride Supplements

Dietary fluoride supplements should be considered for children living in communities in which the community water is not fluoridated or who drink well water that does not contain fluoride.²⁶ Because there are many sources of fluoride in the water supply and in processed food, it is essential that all potential sources of fluoride be assessed before prescribing a dietary supplement, including consideration of differing environmental exposures (eg, dual homes, child care). As a general guideline, if the primary source of water is fluoridated tap or well water, the child will not require fluoride supplementation, even if he or she primarily drinks bottled water, because the teeth are exposed to fluoride through cooking and brushing. The risk of fluorosis is high if fluoride supplements are given to a child consuming fluoridated water.³⁰ Information about the fluoridation levels in many community water systems can be found on the CDC Web site entitled *My Water's Fluoride* (<http://apps.nccdc.gov/MWF/Index.asp>). Not all communities report this information to the CDC; therefore, it may be necessary to contact the local water department to determine the level of fluoride in the community water. Well water must be tested for fluoride content before prescribing supplements; such testing is available in most states through the state or county public health laboratory.

Guidelines for Use

CDC recommendations regarding fluoride supplementation are provided in Table 2. Supplements can be prescribed in liquid or tablet form. Tablets are preferable for children old enough to chew, because they gain an additional topical benefit to the teeth during the chewing process. Liquid supplements are recommended for younger children and should ideally be added to water or put directly into the child's mouth. Addition of the fluoride supplement to milk or formula is not recommended because of the reduced absorption of fluoride in the presence of calcium.³¹ The risk of mild fluorosis can be minimized by health care providers verifying that there are no other sources of fluoride exposure before prescribing systemic fluoride supplements.

Other Sources of Fluoride

Fluoride is present in processed foods and beverages and may be naturally occurring in some areas of the country. The presence of fluoride in juices and carbonated beverages does not counteract the cariogenic nature of these beverages.

Reconstitution of Infant Formula

In a study of infant feeding practices, 70% to 75% of mothers who fed their infants formula used tap water to reconstitute the powdered formula.³² According to CDC data from 2012, approximately 67% of US households using public water supplies received

TABLE 2 Fluoride Supplementation Schedule for Children

Age	Fluoride Ion Level in Drinking Water ^a		
	<0.3 ppm	0.3–0.6 ppm	>0.6 ppm
Birth–6 mo	None	None	None
6 mo–3 y	0.25 mg/d ^b	None	None
3–6 y	0.50 mg/d	0.25 mg/d	None
6–16 y	1.0 mg/d	0.50 mg/d	None

Source: Centers for Disease Control and Prevention.⁴³

^a 1.0 ppm = 1 mg/L.

^b 2.2 mg of sodium fluoride contains 1 mg of fluoride ion.

optimally fluoridated water (between 0.7 and 1.2 ppm).³³

ADA Evidenced-Based Clinical Recommendations

In 2011, the ADA Council on Scientific Affairs examined the existing evidence and made 2 recommendations. The first recommendation supported the continued use of optimally fluoridated water to reconstitute powdered and liquid infant formula, being cognizant of the small risk of fluorosis in permanent teeth. The second recommendation stated that if there was concern about the risk of mild fluorosis, the formula could be reconstituted with bottled (nonfluoridated) water.¹⁸ It should be noted that most bottled water has suboptimal levels of fluoride and that fluoride content is not listed unless it is added.

Community Water Fluoridation

Community water fluoridation is the practice of adding a small amount of fluoride to the water supply. It has been heralded as 1 of the top 10 public health achievements of the 20th century by the CDC.³⁴ Community water fluoridation is a safe, efficient, and cost-effective way to prevent tooth decay and has been shown to reduce tooth decay by 29%.³⁵ It prevents tooth decay through the provision of low levels of fluoride exposure to the teeth over time and provides both topical and systemic exposure. It is estimated that every dollar invested in water fluoridation saves \$38 in dental treatment costs (<http://www.cdc.gov/fluoridation/benefits/>). Currently, although more than 210 million Americans live in communities with optimally fluoridated water, there are more than 70 million others with public water systems who do not have access to fluoridated water.³³ The fluoridation status of a community water supply can be determined by contacting the local water department

or accessing the Web site My Water's Fluoride (<http://apps.nccd.cdc.gov/MWF/Index.asp>).

Recommended Concentration

Water fluoridation was initiated in the United States in the 1940s. In January 2011, the US Department of Health and Human Services proposed a change to lower the optimal fluoride level in drinking water. The proposed new recommendation is 0.7 mg of fluoride per liter of water to replace the previous recommendation, which was based on climate and ranged from 0.7 mg/L in the warmest climates to 1.2 mg/L in the coldest climates.³⁶ The change was recommended because recent studies showed no variation in water consumption by young children based on climate and to adjust for an overall increase in sources of fluoride (foods and beverages processed with fluoridated water and fluoridated mouth rinses and toothpastes) in the American diet.

Evidence Supporting Community Water Fluoridation

Despite overwhelming evidence supporting the safety and preventive benefits of fluoridated water, community water fluoridation continues to be a controversial and highly emotional issue. Opponents express a number of concerns, all of which have been addressed or disproven by validated research. The only scientifically documented adverse effect of excess (nontoxic) exposure to fluoride is fluorosis. An increase in the incidence of mild enamel fluorosis among teenagers has been cited as a reason to discontinue fluoridation, even though this condition is cosmetic with no detrimental health outcomes. Recent opposition has sometimes centered on the question of who decides whether to fluoridate (elected/public officials or the voters), possibly reflecting a recent trend of distrust of the US government. Many opponents believe fluoridation to be mass medication and

call the ethics of community water fluoridation into question, but courts have consistently held that it is legal and appropriate for a community to adopt a fluoridation program.³⁷ Opponents also express concern about the quality and source of fluoride, claiming that the additives (fluorosilicic acid, sodium fluoride, or sodium fluorosilicate), in their concentrated form, are highly toxic and are byproducts of the production of phosphate fertilizer and may include other contaminants, such as arsenic. The quality and safety of fluoride additives are ensured by Standard 60 of the National Sanitation Foundation/American National Standards Institute, a program commissioned by the Environmental Protection Agency (EPA), and testing has been conducted to confirm that arsenic or other substances are below the levels allowed by the EPA.³⁸ Finally, there have been many unsubstantiated or disproven claims that fluoride leads to kidney disease, bone cancer, and compromised IQ. More than 3000 studies or research papers have been published on the subject of fluoride or fluoridation.³⁹ Few topics have been as thoroughly researched, and the overwhelming weight of the evidence—in addition to 68 years of experience—supports the safety and effectiveness of this public health practice.

Naturally Occurring Fluoride in Drinking Water

The optimal fluoride level in drinking water is 0.7 to 1.2 ppm, an amount that has been proven beneficial in reducing tooth decay. Naturally occurring fluoride may be below or above these levels in some areas. Under the Safe Drinking Water Act (Pub L No. 93-523 [1974]), the EPA requires notification by the water supplier if the fluoride level exceeds 2 ppm. In areas where naturally occurring fluoride levels in drinking water exceed 2 ppm, people should consider an alternative water source or home water treatments to reduce the risk of

fluorosis in young children.⁴⁰ Well water should be tested for the level of fluoride; this testing is most commonly performed through the health department.

Fluoride Toxicity

Toxic levels of fluoride are possible, particularly in children, as a result of ingesting large quantities of fluoride supplements. The toxic dose of elemental fluoride is 5 to 10 mg of fluoride per kilogram of body weight.⁴¹ Lethal doses in children have been calculated to be between 8 and 16 mg/kg. When prescribing sodium fluoride supplements, it is recommended to limit the quantity prescribed at one time to no more than a 4-month supply. Parents should be advised to keep fluoride products out of the reach of young children and to supervise their use.

Fluoride Removal Systems

There are a number of water treatment systems that are effective in the removal of fluoride from water,⁴² including reverse osmosis and distillation. Parents should be counseled on the use of these and activated alumina filters in the home and, should they choose to use one that removes fluoride, the potential effect on their family's oral health. Commonly used home carbon filters (eg, Brita [Brita LP, Oakland, California], PUR [Kaz USA, Incorporated, Southborough, MA]) do not remove fluoride. These can be recommended for families who are concerned about heavy metals or other impurities in their home water supply but who wish to retain the benefits of fluoridated water.

SUGGESTIONS FOR PEDIATRICIANS

1. Know how to assess caries risk. As recommended by the AAP's *Oral Health Risk Assessment Timing and Establishment of the Dental Home*⁶ and *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*,⁷ pediatricians should perform oral health risk assessments on all children at preventive visits beginning at 6 months of age. An oral health risk assessment tool has been developed by the AAP/Bright Futures and endorsed by the National Interprofessional Initiative on Oral Health. This tool can be accessed at <http://www2.aap.org/oralhealth/RiskAssessment-Tool.html>. There are currently no validated early childhood caries risk assessment tools. The aforementioned tool is a guide to help clinicians counsel patients about oral health and best identify risk.
2. Know how to assess a child's exposure to fluoride and determine the need for topical or systemic supplements.⁴³
3. Understand indications for fluoride varnish and how to provide it. Fluoride varnish can be a useful tool in the prevention of early childhood caries. Additional training on oral screenings, fluoride varnish indications and application, and office implementation can be found in the Smiles for Life Curriculum Course 6: Caries Risk Assessment, Fluoride Varnish and Counseling⁴⁴ at www.smilesforlifeoralhealth.org. In addition, the AAP Children's Oral Health Web site

is a resource for oral health practice tools (<http://www2.aap.org/oralhealth/PracticeTools.html>).

4. Advocate for water fluoridation in the local community. Public water fluoridation is an effective and safe method of protecting the most vulnerable members of our population from dental caries. Pediatricians are encouraged to advocate on behalf of public water fluoridation in their communities and states. For additional information and water fluoridation facts and detailed questions and answers, see http://www.ada.org/sections/newsAndEvents/pdfs/fluoridation_facts.pdf, <http://www.cdc.gov/fluoridation/>, and <http://www.ilikemyteeth.org>.

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High-Deductible Health Plans

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- *Policy Statement*

POLICY STATEMENT

High-Deductible Health Plans

COMMITTEE ON CHILD HEALTH FINANCING

KEY WORDS

high-deductible health plan, Patient Protection and Affordable Care Act, health reimbursement arrangement, health savings account, patient-centered medical home

ABBREVIATIONS

ACA—Patient Protection and Affordable Care Act
 AAP—American Academy of Pediatrics
 HDHP—high-deductible health plan
 HRA—health reimbursement arrangement
 HSA—health savings account
 PCMH—patient-centered medical home

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abstract

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High-deductible health plans (HDHPs) are insurance policies with higher deductibles than conventional plans. The Medicare Prescription Drug Improvement and Modernization Act of 2003 linked many HDHPs with tax-advantaged spending accounts. The 2010 Patient Protection and Affordable Care Act continues to provide for HDHPs in its lower-level plans on the health insurance marketplace and provides for them in employer-offered plans. HDHPs decrease the premium cost of insurance policies for purchasers and shift the risk of further payments to the individual subscriber. HDHPs reduce utilization and total medical costs, at least in the short term. Because HDHPs require out-of-pocket payment in the initial stages of care, primary care and other outpatient services as well as elective procedures are the services most affected, whereas higher-cost services in the health care system, incurred after the deductible is met, are unaffected. HDHPs promote adverse selection because healthier and wealthier patients tend to opt out of conventional plans in favor of HDHPs. Because the ill pay more than the healthy under HDHPs, families with children with special health care needs bear an increased cost burden in this model. HDHPs discourage use of nonpreventive primary care and thus are at odds with most recommendations for improving the organization of health care, which focus on strengthening primary care.

This policy statement provides background information on HDHPs, discusses the implications for families and pediatric care providers, and suggests courses of action. *Pediatrics* 2014;133:e1461–e1470

INTRODUCTION

High-deductible health plans (HDHPs) have been in existence for many years and were formally codified in 2003 by the Medicare Prescription Drug Improvement and Modernization Act (Pub L No. 108-173). They have become more prevalent in recent years and continue to grow rapidly. The early results of the Patient Protection and Affordable Care Act (ACA) of 2010 (Pub L No. 111-148) indicate that HDHPs will continue to proliferate. Therefore, it is appropriate for the American Academy of Pediatrics (AAP) to revisit HDHPs and their effects on health care for children. This policy statement seeks to enhance understanding of the basic principles of an HDHP, to evaluate how this model comports with the principles of the AAP in providing health care for children, and to make recommendations as to how (and whether) an HDHP should be implemented. Because research data on HDHPs are scarce on many points, as others have observed, “until better evidence emerges, policy

makers and employers will have to use the best available information and commonsense strategies.”¹

DESCRIPTION

For an existing HDHP to receive governmental approval, the plan must have a minimum deductible for 2013 of \$1250 for an individual and \$2500 for a family, with total out-of-pocket expenses (not including the cost of premiums) not to exceed \$6250 for an individual and \$12 500 for a family.² Because pure HDHP policies could discourage use of preventive services, to mitigate this effect, federal law requires HDHPs to cover basic preventive services—well-patient visits, immunizations, screening tests, and Bright Futures preventive services—with no deductibles and no copays.

An optional modification provided by the law is the addition of either a health reimbursement arrangement (HRA), which can be applied to any type of health insurance, or a health savings account (HSA), which is applicable only to an HDHP policy (Table 1).² Both HRAs and HSAs consist of tax-free funds that can be used to pay for out-of-pocket costs (except copays) not paid for by the insurance plan. In 2013, HSA contributions are limited to \$3250 for self-only coverage and \$6450 for family coverage. The mechanics of how funds are withdrawn and how the costs are paid—for instance, by special-purpose debit card or convenience checks that draw down the account—vary depending on the plan.

An HRA is both funded and owned by the employer. If the employee leaves

employment, the funds revert to the employer, unless the employer opts to make them portable. At the discretion of the employer, unused funds may be carried over from year to year.

An HSA is funded by the subscriber, the employer, or both. The HSA account is owned by the subscriber, not the employer, and can move with the subscriber in the event of job change or retirement. In addition, HSA funds can be invested for interest or other gains, and those gains are not taxable. Unused HSA funds can be rolled over into an individual retirement account at age 65.

It is important to understand that if the HRA or HSA is funded by the employer at a sufficiently high level (“fully funded”), patients will not actually suffer financial harm, compared with conventional policies (ie, preferred provider organization, health maintenance organization, point of service, and indemnity plans). Instead, these features will simply induce patients to make a market calculation in seeking care because the need to tap into the savings account resource will be a much more palpable event as compared with the invisible use of resources with conventional policies. It is not known how well funded HRAs and HSAs have been, but common experience indicates that full funding of the accounts is unusual. The average HSA account balance was \$1879 at the end of 2012; the average HSA account balance for accounts opened in 2005 was \$4688.³

HDHPs are becoming a more predominant form of health insurance in the United States as they are increasingly offered by employers and

chosen by subscribers. Although preferred provider organization plans remain the most common offerings by employers and cover more than one-half of covered employees, a 2013 report found that 20% of small companies and 40% of large companies offered an HDHP plan to its employees, and 20% of all employers offered HDHP plans as the only choice.⁴ Whereas in 2006, only 4% of employees were covered by HDHP plans, that number is approximately 20% in 2013. One estimate is that 27% of HDHP enrollees are younger than 20 years.⁵ It is estimated that more than 5 million people younger than 20 years are enrolled in HDHP plans. The health insurance marketplace, under the ACA, offers HDHP plans in the lower tiers, and the ACA allows HDHPs to continue to be offered by employers, so the number of patients covered by HDHP plans is expected to grow further.

Historically, enrollees who have chosen HDHP plans have represented a healthier, wealthier, and better-educated segment of the population. In one study, 64% of HDHP households declared themselves in excellent or very good health, and 89% earned \$50 000 or more per year.⁶ Increasingly, however, HDHPs are being offered by companies with a predominance of low-income workers. In 2012, 44% of covered workers at companies with many low-wage workers faced an annual deductible of \$1000 or more, compared with 29% at firms with many high-wage workers. Across all employers, 34% of insured workers faced a deductible of at least \$1000, with 14% required to pay a deductible of at least \$2000 annually.⁷ Some plans exceed the federal limits for copays or deductibles and are, thus, ineligible for adding the HRA or HSA features; whether they conform or not, however, all HDHP plans have the effect of shifting liability from the insurer to the insured.

TABLE 1 Comparison of HRAs and HSAs

Plan	Tax Savings	Funded by	Annual Rollover of Unused Funds	Portable
HRA	Yes	Employer	At the employer's discretion	At the employer's discretion
HSA	Yes (funds may be invested and earn interest tax free)	Employers and/or employees	Yes	Yes

HDHPs: FOR AND AGAINST

HDHPs represent a market-based approach to one segment of health care: the initial stages of care. In evaluating this approach, it is necessary to look at the detailed effects of HDHPs in practice as well as theory. Because of the scarcity of research data, it is necessary to use inferences and common experience of participants in the field as well as research findings.

For HDHPs

The rise in health care costs has placed unrelenting pressure on employers, who remain the primary purchasers of health insurance products, and on individual purchasers as well. HDHPs offer a simple way to reduce the cost of premiums.

There have been many ideas for health care reform that would reduce total costs, but many of these ideas would be complex to enact, would require the cooperation of many who have vested interests and might be at financial risk from the reforms, and would require legislative authorization. By contrast, HDHPs are simple to implement, requiring the agreement of only the insurance company and the purchaser and no other stakeholder. In addition, legislation authorizing tax exemption for HSAs and HRAs was enacted in 2003. Simplicity of implementation is, no doubt, one of the most attractive aspects of HDHPs.

Employers, employees, and individual subscribers welcome the lower premium level of HDHP plans. Patients tend to accept HDHP deductibles and copays as familiar features, although the levels are higher than in conventional plans. Employees tend not to make the calculation that the financial risk of illness is being transferred to them from the insurer and the business owner. (As HDHP subscribers increased from 2007 to 2011, "Total per capita spending on employer-

sponsored insurance grew at an average annual rate of 4.9 percent ... [and] out-of-pocket medical spending increased at an average annual rate of 8.0%."*) Both individual subscribers and employees who are confident of their ability to make medical choices and to withstand the financial risk may find HDHPs a reasonable choice, especially if linked to an HSA or HRA. Even if they are not confident of their continued good health or medical navigational skill, subscribers of modest means can find the HDHP premium their only affordable choice and may judge running the financial risk of HDHPs preferable to being uninsured.

In addition to these practical considerations, HDHPs have been justified on a theoretical basis. With conventional private insurance, patients are shielded from the financial effect of their purchases when they seek care at the early stages of illness. As a result, patients may use more of the services than they would if they had to pay the actual cost of the services. By contrast, HDHPs require a family to confront the market price of health care services at the point of purchase—a primary care or specialty visit, a laboratory test, or a hospitalization. With "skin in the game," it is hypothesized that patients will have incentive to seek less care for minor reasons, to seek more high-quality and low-cost services, or perhaps to adopt a healthier lifestyle (eg, exercise more, lose weight, improve nutrition, abstain from or reduce smoking and alcohol consumption) to avoid medical expenditures. Because of the patient's direct exposure to the financial consequences of seeking care and his or her expected responses to this burden, HDHPs have been called consumer-directed health plans.⁹

There is evidence that patients with HDHPs do consume less health care than those in other plans.^{10–13} Patients

with HDHPs are prescribed generic drugs more often than other patients, make fewer visits to specialists, are less frequently hospitalized, and have fewer visits to doctors for episodes of illness and make fewer visits within those episodes.¹² HDHPs seem to reduce overall health care costs significantly.¹² How much the employer saves on HDHP policies depends on both the level of HRA or HSA funding and the utilization behavior of the patients. It seems clear, however, that total employer costs of HDHP plans are less than with conventional plans.

There is ample anecdotal evidence from knowledgeable consumers, especially medical professionals, that HDHPs have worked well for their personal health care insurance. They have been able to save money individually and for their office staff/personnel as they advise them on health care decisions, by canny utilization of the system. When they avoid visits for minor illnesses or avoid tests that seem to be an overreach of care, money accumulates in their HSA accounts. When their families are healthy, they reap the reward. Their above-average wealth allows them to withstand the risk of unexpected expenditures for illness. Although less sophisticated consumers may not be able to make such decisions, the HDHP model works for many in this specific group.

Against HDHPs

While acknowledging the success of HDHPs in reducing expenditures, at least in the short term, critics of HDHPs find many flaws with the HDHP strategy.

Appropriateness of Preferentially Decreasing Initial and Lower-Cost Care

Although most agree that cost reduction in the American health care system is essential, HDHP critics insist

that constraining “first-dollar” expenditures by excluding these costs from insurance support, while leaving the higher-cost items covered and thus unconstrained, is a poor choice. Virtually all policies today have deductibles, but the expanded level of the deductible under HDHPs means that a majority of patients will find all their primary care costs to be fully out-of-pocket (except for preventive visits), along with costs that flow from primary care encounters, such as tests, imaging services, medications, and specialty office visits. In addition, because of the higher deductible limit, many procedures will now be encompassed in the out-of-pocket domain, such as hernia repairs, tympanostomy tube placement, and even procedures such as pectus excavatum surgery.

The reason the American health care system is so expensive, however, is not generally considered to be expenditures in the low-cost sector, which represent the majority of encounters. Hospitals, procedures, prescription drugs, and imaging are generally considered the major culprits of the

high cost of medical care, rather than ordinary office services. Increasingly, health policy analysts are assigning the high cost of care to high prices even more than high utilization.¹⁴ The HDHP focus on the low-cost segment of care would thus appear to be misplaced.

Moreover, a significant amount of costs are incurred by a small percentage of high-cost patients. “Nearly two-thirds of health care costs are concentrated in 10% of patients, so to control costs, the focus needs to be on these patients, not the 50% of the population that is relatively healthy and uses just 3% of the health care dollar”¹⁵ (see Fig 1). A way to decrease costs for these patients would be to supply more initial and primary care, not less.¹⁶

The conclusion, then, would be that although cost reduction is important, a better solution than curtailing costs at the low end would be curtailing costs at the high end and with high-intensity users, which are exactly the areas in which deductibles are ineffective.

Lack of Concurrence Between HDHPs and the National Strategy on Health Care Organization

Most health policy experts agree that the United States suffers from insufficient primary care and a surfeit of specialty care.^{17,18} Evidence also indicates that primary care should be the foundation of a highly functional health care system.¹⁹ Primary care is widely thought to be an essential service that, if well-used, saves money for the system. Prescriptions for waste reduction in the medical care system generally exempt primary care and have never targeted primary care for children.²⁰ Although studies have not shown great savings from preventive services, it is reasonable to assume that primary prevention and early detection of disease decrease morbidity and associated costs. It is also widely assumed that having a ready source of primary care prevents excessive use of emergency departments.^{21,22} Starfield asserted that “Several international studies have confirmed the importance of ... low

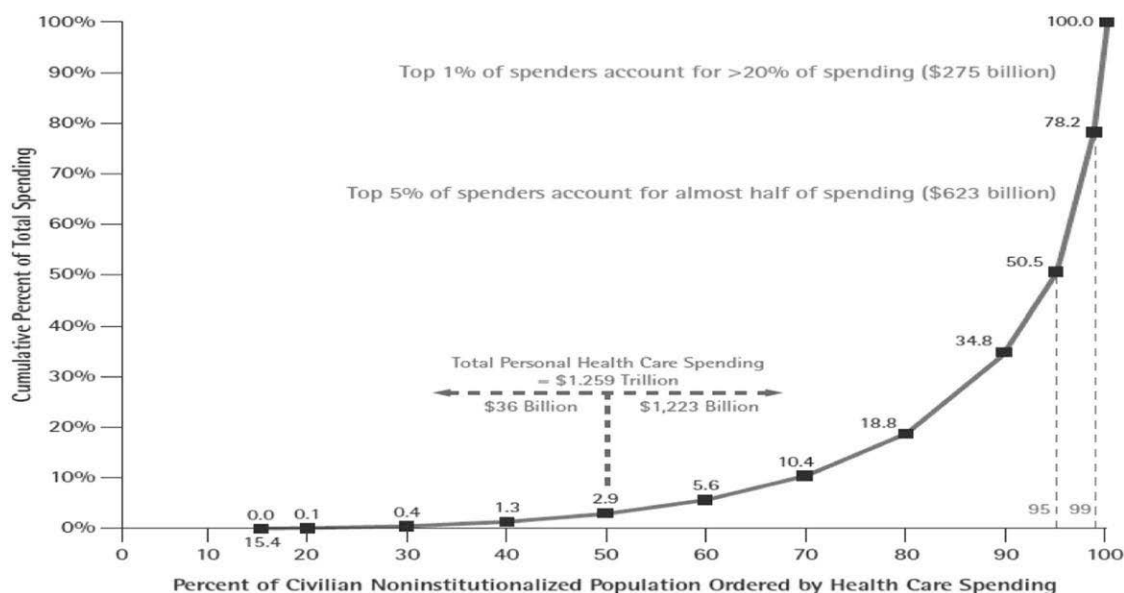


FIGURE 1

Cumulative distribution of personal health care spending, 2009. Reproduced with permission from National Institute for Health Care Management Foundation analysis of data from the 2009 Medical Expenditure Panel Service.

or no cost sharing for primary care services.”²³

One policy response to the need for buttressing primary care has been the patient-centered medical home (PCMH).²⁴ The PCMH is essentially a strengthened primary care office with highly personal care, greater nurse outreach and team care, an emphasis on preventive services and patient registries, education about self-care, and guidance and coordination through the medical care system. The AAP supports the PCMH model and believes that the activated primary care office will be an important component of improved health care organization.²⁵

There are many potential negative effects, however, that HDHPs could have on the strategy of increasing the capacity of American primary care. HDHPs reduce the resources that could and should be invested in primary care; fewer resources expended in a sector will inevitably lead to its degradation. The PCMH strategy requires more resources rather than fewer. In addition, it is widely recognized that 2 prime deterrents to choosing a career in primary care are the imbalance of specialty/primary incomes and the difficulty of managing primary care offices. HDHPs only exacerbate both of these influences (see next section).

Specific Effects on Primary Care

Although HDHPs affect more than just primary care, primary care is perhaps unique in its reliance on relatively small payments for a large number of patients as well as the absence of higher-priced procedures. Expanding the deductible to HDHP levels makes nearly all primary care visits throughout the year (except for preventive visits) subject to out-of-pocket payments. HDHPs will, thus, have a uniquely heavy effect on primary care (as well as cognitive specialty services), making it important to define the effects.

As rational consumers, families confronted with high deductibles will often search for strategies to minimize their out-of-pocket expenditures. They may forgo visits and access information of questionable reliability from sources such as the Internet, neighbors, and the like. They may attempt to substitute telephone conversations for face-to-face visits. They may postpone needed consultations in an effort to address concerns only at well-child visits that are exempt from deductibles. They may decide not to accept physician recommendations for testing or referrals or for follow-up visits to monitor the progress of a disease process. These consumer tactics will affect both health outcomes and processes for patients as well as the operations of the primary care office. In addition, postponement of visits can contribute to the physician's risk of the most common outpatient malpractice complaint—failure to diagnose serious disease early.²⁶

Even though HDHPs offer full coverage of preventive visits without reference to the deductible, HDHP patients tend to stint on preventive care, including immunizations.¹⁰ It is reasonable to believe that early detection of disease suffers, although there have been no studies on that important subject. Continuity of care and the doctor–patient relationship suffer as primary care visits are discouraged and efforts to fulfill the requirements of PCMHs are eroded. Even if a visit would not have revealed serious illness, the calming effect of reassurance to a worried family is part and parcel of excellent medical care, frequently not only allaying anxiety but also averting further use of medical resources, and to the extent that these visits are discouraged, an essential facet of medical care is undermined.

In addition to the effects of HDHPs on care itself, HDHPs also impede the functioning of a pediatric primary care

office. Although the literature might not explore these specifics, they are readily apparent to practicing physicians. Substituting telephone calls for office visits increases practice overhead and decreases income. Excessive discussions of costs increase visit times and, thus, overhead, a point that advocates for spending time discussing finances with patients ignore.²⁷ Bundling sick visits into preventive visits increases the time per visit and may decrease the quality of either the preventive service or the illness service or both, and it is difficult for the office to receive payment for this extra service, despite it being warranted by *Current Procedural Terminology* coding rules.

Finally, it is common experience that billing costs and bad debts are exacerbated by HDHPs. It is usually impossible to know how much a patient will owe for a visit at the checkout station because insurance company Web sites are most often problematic in delivering information that includes both the allowed charge and the deductible remaining. The method of accessing an HRA or HSA account is often opaque. Repeated billings are often necessary, with the attendant overhead, and patients are not infrequently unwilling to pay once they are away from the office and the service, and they are angry that their substantial premiums do not cover all their medical bills. Although some of these factors apply to all insurance, with HDHPs, they recur throughout the year.

Effects on Those Not Choosing HDHPs—Adverse Selection

HDHPs promote adverse selection to health insurance pools as healthier patients gravitate toward the lower premium price HDHP plans, leaving disproportionate numbers of sicker, higher-cost patients. As a result, patients in

conventional plans will pay higher premiums because patients opting for HDHP plans will not be contributing fully to the common pool.

Quality of Care With HDHPs

Although the previous discussion has included observations of quality of care, it seems appropriate to reiterate these effects here. Once again, a lack of studies hampers this effort, but inferences can, nonetheless, be made. Patients frequently make poorly informed decisions in the medical care marketplace. Many of the reductions in care, not only office visits but also tests and consultations, hospitalizations, emergency care, and use of generic drugs in some cases, may be unwarranted.²⁸ One study has shown that patients of modest means postpone visits to emergency departments for serious illnesses.²⁸ This phenomenon is especially pronounced in males.²⁹ A report on Medicare patients has shown that increased cost-sharing has led to decreased physician visits and prescriptions but also to a higher rate of hospitalization.³⁰ Pediatric surgeons report informally that many patients defer elective but important procedures because of cost under an HDHP plan (personal communication, Mary Brandt, MD, professor of surgery and pediatrics, October 12, 2013). Continuity of care and the doctor–patient relationship suffer as primary care visits are discouraged under HDHPs, fewer patients receive preventive care, and fewer patients are fully immunized.¹² The ability of PCMHs to fulfill their mission is undermined. It stands to reason that with increased barriers to seeking initial care, some diagnoses and treatments of illnesses will be delayed. Haviland et al, advocates of HDHPs (referred to as consumer-directed health plans), concede that “for all populations, enrollment in [consumer-directed health plans] ... leads to reductions in care that is

considered beneficial.”¹³ In short, there are many reasons to think that HDHPs decrease quality of care and few to think that they increase it.

HDHPs and Market Mechanisms

HDHP critics question whether market mechanisms are capable of achieving the outcomes that HDHP advocates would wish. Many patients agree with the critics and think that shopping for health care is confusing and inappropriate.³¹ There appear to be many discrepancies between theory and actuality.

A well-functioning market requires well-informed consumers to make rational choices, but many believe that the highly specialized nature of medical decision making, coupled with the profound information asymmetries and uncertainties that characterize these interactions, undermine the ability of market mechanisms to effectively function as expected.³² Certainly, urgent situations are not compatible with “careful shopping,” and the emotional distress accompanying acute illness often compromises rational decision making.³³

Although in the aggregate, patients in HDHPs consume fewer health care resources in response to higher out-of-pocket expenditures, whether this consumption pattern is beneficial remains an open question, as the previous discussion of quality of care under HDHPs illustrates.

There is some evidence that patients tend to equate higher price with higher quality.³⁴ One study indicated that when confronted with a complicated benefit structure, patients often make suboptimal choices.³⁵ An example of this situation is that 80% of patients with HDHPs are unaware that their policies mandate coverage of preventive services free of the deductible or copays (supplying at least part of the explanation for poor prevention

and immunization statistics under HDHPs).³⁶ Patients with chronic illnesses forgo care because of cost.³⁷ Poorer families choose to forgo care more often than families with higher income.³⁸

Market mechanisms depend critically on price signals for consumers to be able to make market decisions, but few prices from clinicians, laboratories, or specialized and diagnostic services are publicly available online or even by request to the office.³⁹ Indeed, prices negotiated between practices and health plans are confidential by the terms of the contract. In addition, the price of a visit is uncertain beforehand, because the level of the service rendered by the physician cannot be predicted. On the other hand, because generic drugs are used more frequently and tests and hospitalizations are used less frequently than with conventional plans, one can surmise that when the primary care physician is involved in the decision making, costs can be alleviated. Economist Victor Fuchs commented, “The idea of sick patients shopping for the lowest-price medical care ... is a fantasy.”⁴⁰

Finally, critics of HDHPs suggest that because patients lack medical knowledge, one of the most important functions of the primary care physician is to guide the patient in choosing among health care options. Thus, it would seem counterintuitive to encourage laypeople not to use the professional knowledge and judgment of a primary care physician, especially when a primary care visit is perhaps the least expensive encounter in the entire spectrum of health care services.

Aspects of HDHPs That Apply Specifically to Children

In health care financing, as with pediatric health care, children are not simply smaller adults. Unfortunately, there is little research on the specific

effects of HDHPs on children. Nonetheless, certain features of these plans pose significant concerns.

Families with small children tend to be high users of primary care services. As such, HDHPs would seem to be particularly inappropriate for them. Because young families are often struggling financially, they will be particularly prone to choosing the lower-premium HDHP plan but then be torn whether to make a visit for a sick child. As noted earlier, the statistics of lower use of preventive visits and lower immunization rates is sobering. Pediatrics places special emphasis on children with special health care needs. These children and their families are specifically disadvantaged by HDHPs. If the family is insured by an HDHP, they will experience higher health care costs than under conventional insurance. If they instead obtain conventional insurance, the premiums and payments they face will be higher because of adverse selection—that is, patients without special needs will be paying less into the common pot.

In addition, some have suggested that there might be legal and ethical aspects to enrolling children in HDHPs. Although adults may be free to take chances with their own lives and health care, the state has a recognized function in protecting children. There is a risk in delaying health care that is exacerbated by financial considerations. It is possible for adults to delay seeking care for their children that turns out to have been necessary. Foreseeing this situation, it might be in the state's interest to disallow HDHPs for children.

Finally, health care for a child costs, on average, about half that for an adult younger than 65 years and approximately one-quarter to one third that for a Medicare patient. The problems of the excessive cost of American health care can hardly be attributed to

children. It would seem to make sense, then, to save money on children's health care only where it is clearly ineffective and inefficient. That public policy in America favors adults and the elderly over children has been well documented; saving on health care of children while the bills of the elderly are unconstrained would seem to be foolish.

The Flow of Resources Within Medical Care Sectors

A subtle point of economic theory is worth mentioning. If HDHPs put pressure on initial care, but there is no such force on the higher-cost items experienced by higher-intensity patients, commercial innovation and research will favor the area where funds flow more freely. Costs will thus not be constrained in the areas where they most need to be, and less effort will be spent on innovation in primary care, which already lacks sufficient attention.

Disparities

Disparities in access, service, and outcomes have been a persistent concern of the AAP and health policy analysts. It is therefore important to reflect on the effect of HDHPs on disparities. If an HDHP plan is linked to a highly funded HRA or HSA, there should be little difference in access between HDHPs and conventional plans. To the extent that the HRA or HSA is less well funded, however, patients who experience high costs and patients who have lower income will experience a higher percentage of their incomes devoted to health care. In some states, the coverage envisioned under the ACA could be as high as 8% to 27% of income for a family of 4 whose income is 200% of the federal poverty level.²¹ Although income effects are not the only cause of disparities, the effects of HDHPs will be to exacerbate the effects of disparate wealth, both by

making HDHP policyholders less able to seek care and by making the premiums of conventional policies more expensive because of adverse selection.

To be more clear: even under the ACA, patients with low incomes—either 100% of the federal poverty level or less or 133% of the federal poverty level or less (depending on the state)—will be eligible for Medicaid. Their access to care will not be limited financially, although it will be constrained by the number of providers accepting Medicaid patients. For patients who have private insurance, the difference in ability to obtain care will depend on the level of their incomes. Higher-income patients will be only somewhat impeded by financial constraints, but those who are just over the Medicaid-eligible line will find the financial constraints more daunting. In other words, it will be the people in the middle, those “just making it” financially, who will feel most strongly the tension of balancing worry over needed care with worry over money. The conclusion, therefore, can be drawn that HDHPs not accompanied by fully funded HRAs or HSAs contribute to disparity of access to care on the basis of income.^{28,38}

SUMMARY

HDHPs are an understandable response by the insurance industry and employers to the rising cost of health care. The major effect of HDHPs is to incentivize patients to balance the perceived need for initial care against the cost before the deductible is met. HDHPs have led to lower expenditures on care by their subscribers. Sophisticated medical care utilizers and healthy and higher-income patients can save significant amounts of money under HDHPs. High funding by employers of HRA and HSA plans can ensure that patients as well as employers benefit.

Critics point out that the lower-cost sectors of health care are less important for

cost savings than higher cost areas that are unaffected by HDHPs; that lower-cost patients are affected by HDHPs, but higher-cost patients are more of a cost problem; that primary care is affected negatively by HDHPs, which goes against established health policy goals; that health care quality might be negatively affected by HDHPs; that health care disparities may be accentuated by HDHPs; that using a market mechanism to induce more patient choice might be inappropriate; and that HDHPs might be particularly inappropriate for children, who are a lower-cost population than adults and who are large utilizers of primary care.

RECOMMENDATIONS

The AAP cautions that HDHPs may be a less desirable way to lower health care costs than other means that can be found, even if “other means” require more work by government, insurance companies, and other health policy participants. Consideration should be given to mandating that HDHPs be offered only to adults and not children.

Benefit Design

1. HDHP policies should permit a generous number of primary care visits to be allowed without the deductible each year or that outpatient visits be exempted from the deductible, as is proposed by the Bipartisan Policy Center for Medicare patients.⁴¹ A list of other important and beneficial services and procedures usually provided by medical subspecialists that would be exempted from HDHP deductibles should be compiled. Examples might be insertion of tympanostomy tubes, appendectomy, and reduction and casting of fractures, for instance.
2. If children are to continue to be offered HDHP coverage, insurers

should define children with certain diagnoses as “children with special needs” using the Maternal and Child Health Bureau’s definition, and eliminate the burden of a deductible for these children.

3. HSA and HRA health savings accounts should be required to be funded at high levels by the purchasing employers.
4. All elements of the PCMH should be included in the plan benefit package and paid, without application of the deductible, appropriate to the relative value units, including telephone and electronic communication services. Insurers should cover and pay appropriately for all services described by the *Current Procedural Terminology* manual.

Insurance Company Administrative Policies

1. Insurance companies issuing HDHP policies should be required to devise procedures so that medical offices can easily and rapidly determine the complete bill of the patient at the time of a visit, enabling the office to try to pursue proper collection from the patient at the time of the visit.
2. Patients with HSA and HRA accounts should be issued debit or credit cards that allow medical offices to access the accounts at the time of service.
3. Because practices will incur significant additional overhead costs in administering HDHPs, insurance companies should compensate practices for those costs. One alternative would be to pay practices per-patient-per-month overhead allowances.
4. Insurers should take positive steps to emphasize the importance of preventive visits to its policyholders and to inform them that such services are not subject to the de-

ductible or copays. Plans should be held responsible for continually assessing the completeness of preventive services utilization by its policyholders and to take appropriate steps as conditions warrant.

5. Because of the complexity of HDHP plans, especially when one considers that each company would have its own specific rules and procedures, insurance companies should ensure that they enable both patients and providers to understand provisions. Handouts for the offices and Web site explanations should be available in real time. Insurance companies should have specifically assigned representatives for each office for general issues and should be able to deal with problems in real time, and insurers should facilitate training of office staff members in handling HDHPs. Materials for patients should specifically counsel patients not to stint on primary care services, especially preventive services.

Actions by the Primary Care Offices

1. A staff member in each office should be knowledgeable enough about HDHPs to be able to explain the concept and the details to a potentially confused patient. Patient handouts describing HDHPs and especially the fact that preventive care is not subject to copays or a deductible would be helpful.
2. Offices should continue to give feedback on problems with HDHPs to the AAP by using the Hassle Factor forms (available online at My AAP at www.aap.org/moc, see More Resources).

Alternative Cost-Reduction Strategies

1. Policy makers should continue to devise alternative strategies that will

reduce costs in ways that do not negatively affect primary care. Examples include reduction of high prices rather than utilization, particularly of hospitals, procedures, pharmaceuticals, and medical devices⁴²; offering incentives and support to practices to serve high utilizers with intensive primary care; increasing use of hospices and decreasing use of ICUs for end-of-life care; promoting accountable care organizations; promoting centers of excellence⁴³; developing further value-based insurance plans; increasing use of publicly reported physician report cards for both primary care and specialists issued by independent practice associations as well as hospitals and medical groups;

enacting tort reform; and many other strategies.^{44,45}

Legislation

1. State governments should take steps to make the knowledge of prices for services at various institutions readily available to the public and primary care offices.
2. The federal government should consider restricting HDHP plans to those older than 18 years.

Research

1. Significant efforts to study the effects of HDHPs, especially on children, should be made. The potential foci of research are multifold and deserving of a report solely

devoted to the topic of the specific needs for research on HDHPs.

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Hypothermia and Neonatal Encephalopathy

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- *Clinical Report*

CLINICAL REPORT

Hypothermia and Neonatal Encephalopathy

abstract

FREE

Data from large randomized clinical trials indicate that therapeutic hypothermia, using either selective head cooling or systemic cooling, is an effective therapy for neonatal encephalopathy. Infants selected for cooling must meet the criteria outlined in published clinical trials. The implementation of cooling needs to be performed at centers that have the capability to manage medically complex infants. Because the majority of infants who have neonatal encephalopathy are born at community hospitals, centers that perform cooling should work with their referring hospitals to implement education programs focused on increasing the awareness and identification of infants at risk for encephalopathy, and the initial clinical management of affected infants. *Pediatrics* 2014;133:1146–1150

BACKGROUND

In 2005, the National Institute of Child Health and Human Development (NICHD) convened a workshop to evaluate the status of knowledge regarding the safety and efficacy of hypothermia as a neuroprotective therapy for neonatal hypoxic-ischemic encephalopathy.¹ Shortly thereafter, the Committee on Fetus and Newborn of the American Academy of Pediatrics published a commentary supporting the recommendation of the workshop that the widespread implementation of hypothermia outside the limits of controlled trials was premature.² In 2010, the *Eunice Kennedy Shriver* NICHD organized a follow-up to the 2005 workshop to review available evidence.³ The purpose of this clinical report is to review briefly the current knowledge regarding the efficacy and safety of therapeutic hypothermia, to point out major gaps in knowledge that were identified at the 2010 workshop, and to suggest a framework for the implementation of hypothermia. The intended audience is neonatal/perinatal medicine practitioners.

PRELIMINARY STUDIES

Neuronal rescue of encephalopathic newborn infants using induced hypothermia is one of the few therapeutic modalities in neonatology that was studied extensively in animal models before clinical application in humans. From animal studies, it was noted that cooling the brain to approximately 32°C to 34°C starting within 5.5 hours after a hypoxic/ischemic insult and continuing to cool for 12 to 72 hours resulted in improved neuropathologic and functional outcomes.⁴ After showing consistent benefit in animal models, the safety, feasibility, and practicality of using induced hypothermia in infants who have neonatal encephalopathy were investigated in

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KEY WORDS

hypothermia, hyperthermia, neonatal encephalopathy, infant, head cooling

ABBREVIATIONS

aEEG—amplitude-integrated electroencephalography

EEG—electroencephalography

CI—confidence interval

NICHD—National Institute of Child Health and Human Development

RR—relative risk

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several small studies. Data from these preliminary clinical studies indicated that reducing body temperature by 2°C to 3°C for a prolonged period of time was possible and that the changes in blood pressure, heart rate, and cardiac output noted were of little clinical significance.^{5–7}

Large Randomized Clinical Trials of Hypothermic Neural Rescue (Table 1)

Six large randomized clinical trials of induced hypothermia for neonatal

encephalopathy were published from 2005 to 2011.^{8–13} Although there were some differences in the method of cooling and selection of subjects, in all trials infants were at least 35 weeks' gestation at birth; randomization was completed within 6 hours of birth; the target temperature was 33.5°C to 34.5°C; the intervention period was 72 hours, followed by slow rewarming (0.5°C/hour); and the primary outcome measure was the combined rate of death or disability, assessed at 18 to 22 months of age. Some trials used preferential head

cooling with mild body cooling,^{8,11} and others used whole-body cooling^{9,10,12,13}; however, all trials continuously monitored both the degree of cooling and core body temperature. In addition, 3 trials used either amplitude-integrated electroencephalography (aEEG) or electroencephalography (EEG) for the assessment of severity of encephalopathy and enrollment of infants.^{8,10,12}

Each of the 6 published trials was powered to detect a difference in the primary composite outcome of death or disability at 18 to 24 months of age, and all showed a benefit with cooling; in 4 of the 6 studies, this reached statistical significance. Rates of death or disability were similar in the control groups for 4 of the 6 studies, suggesting that patient selection and treatment were likely similar in these trials.^{8–10,13} A published meta-analysis that included a small pilot study⁵ as well as the 6 large published clinical trials demonstrated a reduction in the relative risk (RR) of the composite outcome of death or major neurodevelopmental disability at 18 to 24 months of age by 24% (RR, 0.76; 95% confidence interval [CI], 0.69–0.84).¹⁴ A beneficial effect was noted both in infants who had moderate encephalopathy (RR, 0.67; 95% CI, 0.56–0.81) and those who had severe encephalopathy (RR 0.83; 95% CI, 0.74–0.92). The number of infants who need to be treated to prevent 1 infant from dying or becoming disabled is 6 for infants who have moderate encephalopathy and 7 for those who have severe encephalopathy. A review by the Cochrane collaboration that included 11 randomized controlled trials comprising 1505 term and late preterm infants who had moderate/severe encephalopathy demonstrated similar results.¹⁵ The reduction in death or major neurodevelopmental disability to 18 months of age for treated infants was 25% overall; 32% for infants who had moderate encephalopathy and

TABLE 1 Therapeutic Hypothermia Clinical Trials

Clinical Trial	Entry Criteria
CoolCap	Gestational age ≥ 36 weeks and ≤ 6 hours of age AND Apgar score ≤ 5 at 10 minutes after birth OR Continued need for resuscitation at 10 minutes after birth OR pH < 7.00 or base deficit ≥ 16 mmol/L or more on an umbilical cord blood sample or an arterial or venous blood sample obtained within 60 minutes of birth AND Moderate or severe encephalopathy on clinical examination AND Moderately or severely abnormal background of at least 20 minutes' duration or seizure activity on amplitude integrated electroencephalogram (aEEG) after one hour of age
Whole Body Cooling	Gestational age ≥ 36 weeks and ≤ 6 hours of age AND pH ≤ 7.00 or base deficit ≥ 16 mmol/L in an umbilical cord blood sample or any blood sample obtained within the first hour after birth^a AND Moderate or severe encephalopathy on clinical examination
TOBY	Gestational age ≥ 36 weeks and ≤ 6 hours of age AND Apgar score ≤ 5 at 10 minutes after birth OR Continued need for resuscitation 10 minutes after birth OR pH < 7.00 or base deficit ≥ 16 mmol/L on umbilical cord or arterial or capillary blood sample obtained within 60 minutes after birth AND Moderate or severe encephalopathy on clinical examination AND Abnormal background activity of at least 30 minutes' duration or seizures on amplitude integrated electroencephalogram (aEEG)

^a If blood gas is not available or pH is between 7.01 and 7.15 or base deficit is between 10 and 15.9 mmol/L on blood sample obtained within the first hour of birth, two additional criteria are needed: a history of an acute perinatal event (eg, cord prolapse, fetal heart rate decelerations) and either the need for assisted ventilation initiated at birth and continued for 10 minutes or an Apgar score ≤ 5 at 10 minutes after birth.

18% for those who had severe encephalopathy.

Follow-up beyond infancy has been reported for subjects enrolled in the CoolCap trial and the NICHD Whole-Body Cooling trial.^{16,17} Because the follow-up rate at 7 to 8 years of age was only 50% in the CoolCap trial, there were insufficient data to ascertain the long-term risk or benefits of selective head cooling. In the NICHD follow-up study, there was no statistical difference in the composite primary outcome of death or IQ <70 at 6 to 7 years of age between the treated and usual care cohorts ($P = .06$). Hypothermia treatment was associated with a reduction in the secondary outcomes of death (RR, 0.66; 95% CI, 0.45–0.97) and death or cerebral palsy (RR, 0.71; 95% CI, 0.54–0.95).

Observations From Large Clinical Trials

Adverse effects observed with hypothermia were infrequent in the target temperature ranges used in published clinical trials. The most common adverse effects were sinus bradycardia and prolongation of the QT interval on electrocardiogram, both of which are physiologic responses to hypothermia. Reddening or hardening of the skin (systemic hypothermia) and on the scalp (selective head cooling) and subcutaneous fat necrosis occurred rarely. The reported rates of coagulopathy, sepsis, and pneumonia were essentially the same in treated and control infants. When published studies were aggregated in a meta-analysis, the adverse effects of hypothermia included an increase in sinus bradycardia and a significant increase in thrombocytopenia (platelet count <150 000/mm³).¹⁵

Both the TOBY and NICHD trial noted an adverse effect of pyrexia on neurologic outcome among infants allocated to standard care.^{18,19} In both

trials, approximately 30% of the control group had a rectal or esophageal temperature greater than 38°C recorded on at least 1 occasion. The risk for death or disability among infants who had an elevated rectal temperature was increased by threefold in the TOBY trial, whereas in the NICHD trial, the risk for adverse outcome was increased threefold to fourfold, with each degree Celsius increase in the highest quartile of esophageal temperature. It is not known whether the elevated temperatures observed in the 2 trials caused additional brain injury or whether the elevated temperatures were the manifestation of existing hypoxic-ischemic brain injury.

Knowledge Gained From Large Clinical Trials

Approximately 1200 infants were enrolled in the 6 large clinical trials of therapeutic hypothermia. Analyses of aggregate data, as well as data from registries, indicate that moderate hypothermia initiated within 6 hours of birth and continued for 72 hours is a safe and modestly effective neural rescue strategy for infants born at greater than 35 weeks of gestational age who have clinical evidence of moderate or severe neonatal encephalopathy.

Areas of Uncertainty

Because there was little variability among published clinical trials, questions remain regarding the optimal timing for the initiation of cooling and the depth and duration of therapy. There are several ongoing randomized clinical trials that are designed to assess the efficacy of initiating cooling between 6 and 12 hours of age, using a deeper depth of cooling (32°C), or cooling for a longer duration (120 hours) (NCT 01192776, NCT 00614744). In addition, information regarding the safety and efficacy of cooling treatment of encephalopathic infants born

at less than 35 weeks of gestational age is lacking, but preliminary information may be available in the near future (NCT 1793129).

There is also uncertainty regarding the safety and efficacy of initiating cooling before transfer to a center offering therapeutic hypothermia. However, data from the Vermont Oxford Encephalopathic Registry indicate that as many as a third of encephalopathic infants, many of whom were born in other facilities, were not admitted to a neonatal ICU until after 6 hours of age.²⁰ In a study in which active cooling with cool packs was started on arrival of the transport team at the referring center, approximately one-third of the 35 infants had a rectal temperature below 32°C on arrival at the cooling center.²¹ A similar rate of excessive cooling on arrival was noted when passive cooling was used (3 of 18 infants).²² Using a carefully designed protocol for passive cooling at the referral hospital and on transport, Kendall et al noted that 67% of the 39 infants were within target temperature range (33°C–34°C) on arrival at the cooling center, and 11% had a rectal temperature below 32°C.²³ There have been 2 observational studies from the United Kingdom of servo-controlled cooling in the field.^{24,25} Application of this mode of cooling led to significantly less overcooling and greater success in maintaining rectal temperature in the target range when compared with passive cooling.

Clinical Trials of Adjuvant Therapies for Neonatal Encephalopathy

Because the incidence of death and disability remains high after treatment with cooling (approximately 40%), there is an urgent need for additional therapies to further improve outcomes of infants who have acute encephalopathy. Promising neuroprotective agents include antiepileptic drugs, erythropoietin,

melatonin, and xenon. Phase I and II trials of xenon (NCT 00934700, NCT 01545271) and topiramate (NCT 01241019, NCT 01765218) as adjuvant therapy to hypothermia are underway. A phase II study of erythropoietin using doses of 1000 U/kg intravenously in infants undergoing cooling is planned (NCT 01913340) and a phase I and II study of darbepoetin as concurrent therapy with cooling is in progress.²⁶ There is also a phase I–II study assessing the safety and efficacy of clonidine therapy during cooling for neonatal encephalopathy (NCT 01862250).

CONCLUSIONS

1. Medical centers offering hypothermia should be capable of providing comprehensive clinical care, including mechanical ventilation; physiologic (vital signs, temperature) and biochemical (blood gas) monitoring; neuroimaging, including MRI; seizure detection and monitoring with aEEG or EEG; neurologic consultation; and a system in place for monitoring longitudinal neurodevelopmental outcome.
2. Infants offered hypothermia should meet inclusion criteria outlined in published clinical trials (see Table 1). Eligibility criteria include a pH of ≤ 7.0 or a base deficit of ≥ 16 mmol/L in a sample of umbilical cord blood or blood obtained during the first hour after birth,

history of an acute perinatal event, a 10-minute Apgar score of <5 , or assisted ventilation initiated at birth and continued for at least 10 minutes. In addition, a neurologic examination demonstrating moderate to severe encephalopathy is essential. If preferential head cooling is used, an abnormal background activity on either EEG or aEEG also is required.

3. Training programs and infrastructure need to be established and maintained in a highly organized and reproducible manner to ensure patient safety. Each center offering hypothermia therapy needs to develop a written protocol and monitor management and outcomes. Training needs to include awareness and timely identification of infants at risk for encephalopathy and an appropriate assessment of infants who have encephalopathy. Educational endeavors need to involve obstetric care providers; labor, delivery, nursery, and postpartum personnel; and pediatric care providers.
4. Outreach education to community hospitals needs to be implemented. Specific issues include the awareness and timely identification of infants at risk for encephalopathy and prevention of extreme hypothermia and hyperthermia.

5. Cooling infants who are born at less than 35 weeks' gestation or those who have mild encephalopathy, cooling for longer than 72 hours, cooling at a temperature lower than that used in published clinical trials, and the use of adjuvant therapies should only be performed in a research setting and with informed parental consent.

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Immersion in Water During Labor and Delivery

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- *Clinical Report*

CLINICAL REPORT

Immersion in Water During Labor and Delivery

abstract

FREE

Immersion in water has been suggested as a beneficial alternative for labor, delivery, or both and over the past decades has gained popularity in many parts of the world. Immersion in water during the first stage of labor may be associated with decreased pain or use of anesthesia and decreased duration of labor. However, there is no evidence that immersion in water during the first stage of labor otherwise improves perinatal outcomes, and it should not prevent or inhibit other elements of care. The safety and efficacy of immersion in water during the second stage of labor have not been established, and immersion in water during the second stage of labor has not been associated with maternal or fetal benefit. Given these facts and case reports of rare but serious adverse effects in the newborn, the practice of immersion in the second stage of labor (underwater delivery) should be considered an experimental procedure that only should be performed within the context of an appropriately designed clinical trial with informed consent. Facilities that plan to offer immersion in the first stage of labor need to establish rigorous protocols for candidate selection, maintenance and cleaning of tubs and immersion pools, infection control procedures, monitoring of mothers and fetuses at appropriate intervals while immersed, and immediately and safely moving women out of the tubs if maternal or fetal concerns develop. *Pediatrics* 2014;133:758–761

INTRODUCTION

Immersion in water has been suggested as a beneficial alternative for labor, delivery, or both and over the past decades has gained popularity in many parts of world.^{1–4} Approximately 1% of births in the United Kingdom include at least a period of immersion,⁵ and a 2006 joint statement from the Royal College of Obstetricians and Gynecologists and Royal College of Midwives supported immersion in water during labor for healthy women with uncomplicated pregnancies and stated that to achieve best practice with water birth, it is necessary for organizations to provide systems and structure to support this service.⁶ The prevalence of this practice in the United States is unknown, because such data are not collected as part of

AMERICAN ACADEMY OF PEDIATRICS Committee on Fetus and Newborn and AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS Committee on Obstetric Practice

KEY WORDS

labor, delivery, water birth, immersion, perinatal care

ABBREVIATIONS

CI—confidence interval

RCT—randomized controlled trial

RR—risk ratio

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The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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vital statistics. A 2001 survey found that at least 143 US birthing centers offered immersion in water during labor, delivery, or both.⁷ A 2005 commentary by the Committee on Fetus and Newborn of the American Academy of Pediatrics did not endorse underwater birth.⁸ This clinical report reviews the literature concerning the reported risks and benefits of immersion in water during labor and delivery.

EVIDENCE REGARDING IMMERSION IN WATER DURING LABOR AND DELIVERY

Before examining available evidence concerning immersion during childbirth, it is important to recognize the limitations of studies and evidence in this area. Most published articles that recommend underwater births are retrospective reviews of a single center experience, observational studies using historical controls, or personal opinions and testimonials, often in publications that are not peer reviewed.^{1–3,9–11} Also of importance, there are no basic science studies in animals or humans to confirm the physiologic mechanisms proposed to underlie the reported benefits of underwater births.

Other issues, in addition to the nature and design of studies, complicate the interpretation of the published findings, including the absence of a uniform definition of the exposure itself. Often, immersion is referred to as “underwater birth,” but effects and outcomes may be different for immersion during the first stage and second stage of labor. This clinical report, accordingly, avoids the term underwater birth and makes an effort to distinguish data and outcomes related separately to immersion in the first stage and second stage of labor. Not all studies, however, distinguish when in the course of labor and delivery immersion was undertaken.

Outcomes indicating safety or risk in association with immersion at 1 stage may not translate into equivalent outcomes at a different stage of labor; specifically, safety during labor may not translate into safety during delivery. In addition to this important limitation, immersion therapies have varied between studies in the duration of immersion, the depth of the bath or pool, the temperature of the water, and whether or not agitation (jets or whirlpool) was used. In considering the evaluation of outcomes, it is important to note that health care providers involved in providing or studying immersion therapy are not masked to either the treatment or outcomes, and especially in nonrandomized studies, outcomes may be influenced by differences in the environment attending a particular choice of delivery. Finally, most trials of immersion therapy are small, which limits their power to detect rare outcomes.

Randomized controlled trials (RCTs) would be ideal to address many of the aforementioned concerns. A 2009 Cochrane review identified 12 relevant and appropriately designed RCTs of immersion during labor, which involved 3243 women. Nine of these trials involved immersion during the first stage of labor alone (1 of 9 trials compared early versus later immersion during the first stage), 2 trials involved first stage and second stage of labor, and 1 trial involved comparing only the second stage of labor with the controls. Even among these RCTs, however, some of the aforementioned limitations remain, including concerns about power and how the absence of blinding might affect definition of outcomes. The systematic review also noted that most trials have small sample sizes and, thus, a high risk of bias. These factors limit comparison across trials and the reliability and validity of the trial findings.⁵

PROPOSED BENEFITS FROM IMMERSION DURING LABOR AND DELIVERY

There have been claims concerning the positive effects of immersion during labor.^{12–14} Immersion is known to affect maternal cardiovascular physiology as hydrostatic pressure promotes increased venous return and mobilization of extravascular fluid and edema.^{15,16} In part as a result of these effects, proponents of underwater immersion during labor and delivery argue that there are a variety of benefits to such treatment, including a decrease in perinatal pain, a greater sense of well-being and control, and a decreased rate of perineal trauma. Some advocates argue that immersion during labor and delivery decreases maternal stress and stress-associated hormone levels. It could also potentially benefit the newborn infant with a gentler transition from the in utero to ex utero environment.^{1–7}

Individual retrospective analyses and case series argue in support of 1 or more of the benefits listed previously, but among RCTs studying immersion in the first stage of labor that were included in the 2009 Cochrane systematic review,⁵ results were inconsistent. Although many individual RCTs reported no benefit, the combined data indicated that immersion during the first stage of labor was associated with decreased use of epidural, spinal, or paracervical analgesia among those allocated to water immersion compared with controls (478/1254 vs 529/1245; risk ratio [RR] 0.90; 95% confidence interval [CI], 0.82 to 0.99; 6 trials). There was a reduction in duration of the first stage of labor (mean difference –32.4 minutes; 95% CI, –58.7 to –6.13). However, considering each of these effects (particularly the latter), it is difficult to know how factors other than immersion, such as the structure of care (including health

care providers and timing and frequency of examinations) affected outcome. Furthermore, there were no differences in perineal trauma or tears (RR, 1.16; 95% CI, 0.99 to 1.35; 5 trials) or need for either assisted vaginal deliveries (RR, 0.86; 95% CI, 0.71 to 1.05; 7 trials) or cesarean delivery (RR, 1.21; 95% CI, 0.87 to 1.65; 8 trials) between those allocated to the immersion and control arms in the meta-analysis results.

Among the 2 trials that reported outcomes from immersion in the second stage of labor included in this systematic review,⁵ the only difference in maternal outcomes from immersion during the second stage was an improvement in satisfaction among those allocated to immersion in 1 trial. None of the individual trials or the Cochrane systematic review⁵ has reported any benefit to the newborn infant from maternal immersion during labor or delivery.

REPORTED COMPLICATIONS FROM IMMERSION DURING LABOR AND DELIVERY

Individual case reports and case series have noted complications for the mother and the neonate^{17–25} that highlight potential risks from immersion during labor and delivery. Because the denominators are not uniformly reported, the exact incidence of complications is difficult to assess. Some of the reported concerns include higher risk of maternal and neonatal infections, particularly with ruptured membranes; difficulties in neonatal thermoregulation; umbilical cord avulsion and umbilical cord rupture while the newborn infant is lifted or maneuvered through and from the underwater pool at delivery, which leads to serious hemorrhage and shock; respiratory distress and hyponatremia that results from tub-water aspiration (drowning or near drowning); and seizures and perinatal asphyxia.²³

Among this list of complications, given its potential seriousness, the possibility of a neonate aspirating water during birth while immersed has been the focus of understandable concern. Alerdice et al²⁶ summarized case reports of adverse neonatal outcomes, including drownings and near drownings. The case reports included immersion births in hospitals and at home. Subsequently, a study by Byard and Zuccollo reported 4 cases of severe respiratory distress in neonates after water birth, 1 of whom died of overwhelming sepsis from *Pseudomonas aeruginosa*.¹⁹ Although it has been claimed that neonates delivered into the water do not breathe, gasp, or swallow water because of the protective “diving reflex,” studies in experimental animals and a vast body of literature from meconium aspiration syndrome demonstrate that, in compromised fetuses and neonates, the diving reflex is overridden,^{27,28} which leads potentially to gasping and aspiration of the surrounding fluid.

Morbidity and mortality, including respiratory complications, suggested in case series were not seen in the 2009 Cochrane synthesis of RCTs, which concluded that “there is no evidence of increased adverse effects to the fetus/neonate or woman from laboring in water or water birth.”⁵ This conclusion, however, should be tempered by several concerns, including the issue of the power of the sample size to identify rare but potentially serious outcomes. In this regard, in an RCT²⁹ excluded from the Cochrane analysis (because included labors all involved dystocia), 12% of neonates who were delivered in the immersion arm required admission to the NICU, as compared with none in the group delivered without immersion.

SUMMARY

Immersion in water during the first stage of labor may be appealing to

some and may be associated with decreased pain or use of anesthesia and decreased duration of labor; however, there is no evidence that immersion during the first stage of labor otherwise improves perinatal outcomes. Immersion therapy during the first stage of labor should not prevent or inhibit other elements of care, including appropriate maternal and fetal monitoring.

In contrast, the safety and efficacy of immersion in water during the second stage of labor have not been established, and immersion in water during the second stage of labor has not been associated with maternal or fetal benefit. Given these facts and case reports of rare but serious adverse effects in the newborn, the practice of immersion in the second stage of labor (underwater delivery) should be considered an experimental procedure that only should be performed within the context of an appropriately designed clinical trial with informed consent.

Although not the focus of specific trials, facilities that plan to offer immersion in the first stage of labor need to establish rigorous protocols for candidate selection, maintenance and cleaning of tubs and immersion pools, infection control procedures, monitoring of mothers and fetuses at appropriate intervals while immersed, and protocols for moving women from tubs if urgent maternal or fetal concerns develop.

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Immunization for *Streptococcus pneumoniae* Infections in High-Risk Children

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- *Policy Statement*

POLICY STATEMENT

Immunization for *Streptococcus pneumoniae* Infections in High-Risk Children

abstract

FREE

Routine use of the pneumococcal conjugate vaccines (PCV7 and PCV13), beginning in 2000, has resulted in a dramatic reduction in the incidence of invasive pneumococcal disease (IPD) attributable to serotypes of *Streptococcus pneumoniae* contained in the vaccines. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommend the expanded use of PCV13 in children 6 through 18 years of age with certain conditions that place them at elevated risk of IPD. This statement provides recommendations for the use of PCV13 in children 6 through 18 years. A single dose of PCV13 should be administered to certain children in this age group who are at elevated risk of IPD. Recommendations for the use of PCV13 in healthy children and for pneumococcal polysaccharide vaccine (PPSV23) remain unchanged. *Pediatrics* 2014;134:1230–1233

INTRODUCTION

Invasive disease attributable to *Streptococcus pneumoniae* remains a significant public health problem in children despite widespread use of pneumococcal conjugate vaccines (PCV7 and PCV13; Prevnar; Pfizer, Inc, New York, NY) in US infants 2 through 59 months of age. After the introduction of PCV7 and subsequently PCV13, dramatic decreases in invasive pneumococcal disease (IPD) attributable to vaccine serotypes were noted in young children. However, IPD caused by vaccine serotypes continues to occur in older children with immunodeficiency and certain other high-risk conditions, prompting the need for vaccination recommendations to include these populations.

BACKGROUND AND RATIONALE

S pneumoniae is a leading cause of serious infections, including sepsis and meningitis, and accounts for significant morbidity and mortality in the United States.¹ PCV13 was licensed by the Food and Drug Administration for prevention of IPD and otitis media in infants and young children in February 2010, when it replaced PCV7.² PCV13 is recommended for all children 2 through 59 months of age and for children 60 through 71 months of age with chronic medical conditions (eg, heart disease and diabetes); immunocompromising conditions (eg, HIV infection), including functional or anatomic asplenia, including sickle cell disease; cerebrospinal fluid (CSF) leaks; or cochlear implants (Table 1). For children 6 through 18 years with these same high-risk conditions,

COMMITTEE ON INFECTIOUS DISEASES

KEY WORDS

pneumococcal vaccine, invasive pneumococcal disease, immunization, PCV13, PPSV23

ABBREVIATIONS

ACIP—Advisory Committee on Immunization Practices

CDC—Centers for Disease Control and Prevention

CI—confidence interval

CSF—cerebrospinal fluid

IPD—invasive pneumococcal disease

PCV—pneumococcal conjugate vaccine

PPSV—pneumococcal polysaccharide vaccine

RR—rate ratio

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(Continued on last page)

TABLE 1 Underlying Medical Conditions That Are Indications for Pneumococcal Immunization Among Children, by Risk Group^a and Recommended Vaccines

Risk Group	Condition	PCV13		PPSV23	
		Recommended	May Be Considered	1 Dose	Repeat Dose ^b
Immunocompetent children	Chronic heart disease ^c		X	X	
	Chronic lung disease ^d		X	X	
	Diabetes mellitus		X	X	
	CSF leaks	X		X	
	Cochlear implant	X		X	
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies	X		X	X
	Congenital or acquired asplenia or splenic dysfunction				
Children with immunocompromising conditions	HIV infection	X		X	X
	Chronic renal failure and nephrotic syndrome	X		X	X
	Diseases associated with treatment with immunosuppressive drugs or radiation therapy,	X		X	X
	including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation	X		X	X
	Congenital immunodeficiency ^e	X		X	X

^a Centers for Disease Control and Prevention. Licensure of a 13-valent pneumococcal conjugate vaccine (PCV13) and recommendations for use among children. Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2010;59(9):258–261.

^b Repeat PPSV23 doses should be 5 y after the first dose.

^c Particularly cyanotic congenital heart disease and cardiac failure.

^d Including asthma, if treated with prolonged high-dose oral corticosteroids.

^e Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

only PPSV23 has been routinely recommended, although there has been a permissive and off-label recommendation by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) for use of PCV13.²

In June 2012, the ACIP recommended routine use of PCV13 in addition to PPSV23 for PCV13-naïve adults ≥ 19 years of age with immunocompromising conditions, including functional or anatomic asplenia, including sickle cell disease; CSF leaks; or cochlear implants.³ In June 2013, the ACIP recommended routine use of PCV13 for children 6 through 18 years of age with these same conditions who have not previously received PCV13.⁴ PCV13 should be administered to these children regardless of whether they received PCV7 or PPSV23 previously. Recommendations for PPSV23 use for children remain unchanged.

EVIDENCE TO SUPPORT THE RECOMMENDATION

Pneumococcal conjugate vaccines have decreased the rates of IPD directly in

vaccinated children and indirectly (herd protection) in unvaccinated people.² From 2007 through 2009, the average annual incidence of IPD among children 6 through 18 years of age was 2.6 cases per 100 000 population, with 57% of IPD caused by serotypes included in PCV13 (CDC, Active Bacterial Core surveillance 2007–2009, unpublished data, 2013). Among immunocompromised children 6 through 18 years of age, 49% of IPD was caused by serotypes included in PCV13, and an additional 23% of IPD was caused by serotypes included in PPSV23. Incidence of IPD caused by serotypes included in PCV13 among children 6 through 18 years of age with hematologic malignancies was estimated at 1282 per 100 000 population. Compared with children without this condition, this is a rate ratio (RR) of 822 (95% confidence interval [CI], 687–983). For children with HIV infection, the incidence was 197 per 100 000 population (RR, 122; CI, 94–161), and for children with sickle cell disease, the incidence was 56 (RR, 27; CI, 9–73) (CDC, Active Bacterial Core surveillance 2007–2009, unpublished data, 2013). Children

with certain chronic diseases (eg, cardiac or lung disease) are also known to have elevated risk of IPD but at levels lower than those among children with HIV infection.^{2,5}

PCV13 Efficacy and Safety Among Immunocompromised People

Studies of pneumococcal conjugate vaccines containing similar but fewer antigens have been conducted among people with immunocompromising conditions. From a randomized controlled trial among HIV-infected children 2 through 45 months of age in South Africa, the efficacy of a 9-valent pneumococcal conjugate vaccine (PCV9) was estimated as 65% (CI, 24%–86%) against IPD and 13% (CI, –7%–29%) against radiologically confirmed pneumonia.⁶ Vaccine efficacy of PCV7 against IPD caused by a serotype contained in the vaccine in HIV-infected adults in Malawi was estimated at 74% (CI, 30%–90%).⁷ An observational study conducted in the United States among children ≤ 10 years of age with sickle cell disease estimated vaccine effectiveness against IPD to be 81% (CI, 19%–96%) among those who

received ≥ 1 dose of PCV7.⁸ Although vaccine efficacy and effectiveness have been demonstrated, the duration of protection against IPD remains unknown.

In January 2013, the US Food and Drug Administration approved use of PCV13 in healthy children 6 through 17 years of age for the prevention of IPD caused by serotypes included in the vaccine. Current evidence supports the safety of PCV13 in children with immunocompromising conditions.^{9,10} An open-label, single-arm study of 158 children 6 through 18 years of age with sickle cell disease who previously received PPSV23 demonstrated that 1 dose of PCV13 was safe.⁹ The most common adverse events reported within 7 days of 1 dose included myalgia (74.8%), fatigue (66.1%), and headache (53.6%); less common events included arthralgia (39.8%), fever (26%), vomiting (15.4%), and diarrhea (13.3%). Severe adverse events were reported among 8% of the children and included sickle cell pain crisis (4%), acute chest syndrome (2%), and fever (2%). In a PCV7 efficacy trial among HIV-infected children, the most common adverse events were severe induration, erythema, fever, and restricted leg movement; no serious adverse events were reported.¹⁰

PPSV23 in Immunocompromised Children

PPSV23 contains 12 of the serotypes included in PCV13, plus 11 additional serotypes, which account for 23% of IPD cases among immunocompromised children 6 through 18 years of age (CDC, Active Bacterial Core surveillance 2007–2009, unpublished data, 2013). PPSV23 currently is recommended for children ≥ 2 years of age with elevated risk of IPD.⁴ Given the high burden of IPD caused by serotypes included in PPSV23 but not in PCV13, broader protection should be provided through use of both PCV13 and PPSV23.

POLICY RECOMMENDATIONS

The following recommendation is new and not included in any previous American Academy of Pediatrics (AAP) policy.

Children 6 Through 18 Years of Age With Conditions That Place Them at Highest Risk

A single dose of PCV 13 should be given to children 6 through 18 years of age who have immunocompromising conditions, including HIV infection and functional or anatomic asplenia, including sickle cell disease; CSF leaks; or cochlear implants and who have not previously received PCV13. PCV13 should be administered to these children regardless of whether they received PCV7 or PPSV23 previously. Children in this group who have not previously been immunized with PPSV23 should receive a dose of PPSV23 ≥ 8 weeks after their dose of PCV13. For children in this group who have been previously immunized with PPSV23, a single dose of PCV13 should be given ≥ 8 weeks after the PPSV23 dose.

The following recommendation is unchanged from previous AAP policy.

Children 6 Through 18 Years of Age With Conditions That Place Them at Highest Risk

A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for children with anatomic or functional asplenia, including sickle cell disease, HIV infection, or other immunocompromising conditions. This second dose is not recommended for children with cochlear implants or CSF leaks.

Immunocompetent Children 6 Through 18 Years of Age With Conditions That Place Them at Elevated Risk

Immunocompetent children who have underlying medical conditions that place them at elevated risk for IPD (Table 1)

may also receive PCV13 if they have not previously received PCV13 and regardless of whether they have received PCV7 in the past. If both PCV13 and PPSV23 are used, PCV13 should be administered first, and the administration of PPSV23 should follow at an interval of ≥ 8 weeks. A second dose of PPSV23 is not recommended for this group of children.

Recommendations for the use of PCV13 for children younger than 60 months of age and the use of PPSV23 for children of all ages are unchanged. PCV13 is approved for the Vaccines for Children program through 18 years of age, and the vaccine will be covered by the Vaccine Injury Compensation Program. PPSV23 is not covered by the Vaccine Injury Compensation Program.

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Insufficient Sleep in Adolescents and Young Adults: An Update on Causes and Consequences

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- *Technical Report*

TECHNICAL REPORT

Insufficient Sleep in Adolescents and Young Adults: An Update on Causes and Consequences

Judith Owens, MD, MPH, FAAP, ADOLESCENT SLEEP WORKING GROUP, and COMMITTEE ON ADOLESCENCE

KEY WORDS

adolescents, caffeine, car crashes, media use, obesity, sleep loss, sleepiness

ABBREVIATIONS

REM—rapid eye movement

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abstract

FREE

Chronic sleep loss and associated sleepiness and daytime impairments in adolescence are a serious threat to the academic success, health, and safety of our nation's youth and an important public health issue. Understanding the extent and potential short- and long-term repercussions of sleep restriction, as well as the unhealthy sleep practices and environmental factors that contribute to sleep loss in adolescents, is key in setting public policies to mitigate these effects and in counseling patients and families in the clinical setting. This report reviews the current literature on sleep patterns in adolescents, factors contributing to chronic sleep loss (ie, electronic media use, caffeine consumption), and health-related consequences, such as depression, increased obesity risk, and higher rates of drowsy driving accidents. The report also discusses the potential role of later school start times as a means of reducing adolescent sleepiness. *Pediatrics* 2014;134:e921–e932

INTRODUCTION

Since the publication of the American Academy of Pediatrics technical report on excessive sleepiness in adolescents in 2005,¹ there have been a considerable number of articles published pertaining to sleep. These articles expand on many of the topics raised in the original report and add a number of new important health issues not previously or minimally discussed (ie, short sleep and its association with obesity, caffeine/stimulant use). The previous technical report provided an overview of the profound changes in sleep–wake regulation and circadian biology occurring during adolescence, outlined factors (ie, parental influence, school start times) contributing to insufficient sleep in adolescents, and summarized consequences such as negative impacts on mood, attention, and school performance. It also focused in particular on clinical sleep disorders such as insomnia, narcolepsy, and restless legs syndrome contributing to daytime sleepiness in adolescents. The new material in the present report adds to what is known about the extent of sleep restriction in the adolescent population and reinforces the importance of recognizing insufficient sleep both as a key public health issue and one that is immediately relevant to pediatric practice.

The focus of this updated technical report is on insufficient sleep, specifically as a consequence of voluntary sleep restriction. It should

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be noted that such terms as insufficient sleep, inadequate sleep, short sleep duration, sleep loss, and sleep restriction are used interchangeably and as generic descriptive terms only and do not imply specific amounts but rather “less sleep than needed.”

Insufficient sleep in adolescents was recognized as a serious health risk in 2010 in a jointly sponsored American Medical Association/American Academy of Sleep Medicine resolution acknowledging the problem.² Furthermore, objectives for Sleep Health, a new topic in Healthy People 2020,³ specifically includes reducing adolescent sleep loss: “SH-3: Increase the proportion of students in grades 9 through 12 who get sufficient sleep” (defined as ≥ 8 hours). A second focus of the present report is on unhealthy sleep behaviors (ie, poor “sleep hygiene”) in teenagers, including irregular sleep–wake patterns, electronic media use in the bedroom, and excessive caffeine use. A third focus is on the myriad of potential consequences of inadequate sleep in adolescents, including depression/suicidal ideation, obesity, car crashes attributable to drowsiness, and poor academic performance.

EPIDEMIOLOGIC STUDIES OF SLEEPING ADOLESCENTS

Epidemiologic studies of sleep typically rely on self- or parent-reported questionnaire data to document adolescent sleep patterns and the factors affecting them. The key advantage of this method is the ease of assessment of large sample sizes. As a result, epidemiologic studies can determine sleep patterns across the full adolescent age range with less potential sampling bias than smaller case-control studies. Consistent with other methodologic approaches, the consensus finding across epidemiologic studies is that both younger^{4–6} and older^{4,7–11} adolescents are not getting enough sleep. It is important to

note that studies comparing self-reported sleep duration with objectively measured sleep amounts (ie, with actigraphy) suggest that self-reports of sleep often overestimate actual sleep duration, signifying that the problem of chronic sleep loss in adolescents may be even greater than the data indicate.¹² US-based^{4,13} and international studies^{5,6,14} revealed that as students get older, sleep durations decline. The National Sleep Foundation Sleep in America Poll⁴ found that by the 12th grade, 75% of students self-reported sleep durations of less than 8 hours of sleep per night compared with 16% of sixth graders. Furthermore, although 30% to 41% of sixth through eighth graders were getting 9 or more hours of sleep, only 3% of 12th graders reported doing so. Adolescents often attempt to address the accumulated weekday sleep debt during the weekend, when oversleep (the difference between weekday and weekend sleep durations) of up to 2 or more hours is commonly reported.^{4,7,8,15,16}

Comparisons with other countries show similar patterns of decreased sleep durations with increasing age among adolescents. For example, in Northern Taiwan,⁵ Germany,¹⁴ and India,¹⁷ average sleep duration dropped to below 8 hours for high school–aged students. The most precipitous drop was reported in 2005 for more than 1400 South Korean adolescents, for whom the average duration of sleep was 4.9 hours.⁶ In general, studies have demonstrated similar weekend sleep durations across countries, but weekday sleep durations tend to vary greatly.^{5,9} In contrast, Australian adolescents seem to do comparatively well, with students 17 years and older reporting average sleep durations between 8.5 and 9.1 hours.¹⁸ The difference between weeknight and weekend sleep durations also was not large, with weekend durations reported at 9.3 hours. Interestingly, although data on school start times in the Australian

study were not presented, the average reported wake times on school days was 7:00 AM or later, suggesting that the schools these students attended did not start before 8:00 AM.

A number of studies have indicated that sleep health disparities exist and that adults,¹⁹ children, and adolescents^{20–22} from families with low income or of racial or ethnic minorities may be at even greater risk of poor-quality and insufficient sleep. For example, in a recent study of middle school students, appropriate timing and consistency of both weeknight and weekend sleep schedules were inversely correlated with low socioeconomic status and specific household/neighborhood variables (eg, overcrowding, noise levels, safety concerns).²³ This relationship may have important health implications. For example, a recent study suggested that less sleep was a predictor of obesity risk in African-American adolescents but not in white adolescents.²⁴ “Missed” sleep was also reported to be an important factor in asthma morbidity, especially in Latino children.²⁵ However, higher socioeconomic status is not necessarily protective because studies have also shown that youth from households with higher socioeconomic status have shorter sleep durations.^{16,26}

For older adolescents, additional environmental factors, such as after-school employment,¹⁶ striving for good grades,^{5,6,12} socializing,^{27,28} participation in sports and other extracurricular activities, and lack of parental monitoring or rules about bedtimes, can further interfere with sleep durations.^{6,29,30} School start times are reviewed later in the present report.

In summary, short sleep durations, coupled with evidence of daytime sleepiness (eg, increased self-reported sleepiness ratings,^{5,6,11,31} daytime napping,^{5,14,26} weekend oversleeping,^{6,10,14,32} need for assistance in waking⁶), as well as increased use of fatigue countermeasures

(eg, excessive caffeine consumption^{4,5,15}), all indicate that adolescents are sleeping fewer hours than they need. The clear and consistent message is that middle and high school students are not getting enough sleep and that this issue is a chronic problem worldwide. In addition, the health and behavioral outcomes linked to restricted sleep, as further detailed in the following sections, are alarming. These outcomes include increased risk of car crashes,^{4,33} delinquent behaviors,²⁷ depression,^{8,10,34} and psychological stress.³⁵

FACTORS CONTRIBUTING TO INSUFFICIENT SLEEP IN ADOLESCENTS

Influence of Biological Processes on Adolescent Sleep

The association of early adolescent development/pubertal onset and a more evening-type circadian phase preference (ie, preferred timing of sleep and wake as well as daytime activities) has been documented since the 1990s.³⁶ The behavioral result of this biological process is most clear in the timing of sleep, particularly for weekends. For example, Roenneberg et al³⁷ measured the midpoint of weekend sleep in European schoolchildren and revealed a marked linear delay of 2 (girls) to 3 (boys) hours across the second decade, roughly 12 to 18 minutes later with each year of age. The reversal of this delayed weekend sleep pattern may be a “biological marker for the end of adolescence.”

Recent data have indicated that another process involved in regulating sleep timing seems to be altered to favor late nights across adolescent development. This process, called sleep–wake homeostasis, can be thought of as the system that accounts for greater pressure to sleep as one stays awake longer. Data collected with 2 different paradigms to estimate the rate of buildup of sleep pressure in prepubertal versus postpubertal adolescents indicate that

more mature adolescents accumulate this sleep pressure at a slower rate.^{38,39}

Maturational changes to these 2 bioregulatory processes begin in adolescents as young as middle school and present a major challenge for young people to fall asleep in the early evening and to wake refreshed/restored in the early morning to attend school. The most prominent factors in this regard are evening and nighttime screen use and social networking, both of which have increased markedly in the 21st century.⁴⁰ Going to bed later and waking later on weekends than on weekdays reflects the biology of circadian rhythm and is also a response to insufficient weekday sleep. Later sleep timing and catch-up sleep on the weekends further delay the signal for the biological night (ie, melatonin production) and dissipate residual sleep pressure.⁴¹ In summary, the combination of biologically driven processes with modern lifestyles and social obligations minimize the opportunities for adolescents to obtain adequate sleep.

Electronic Media and Sleep

Today's adolescents and young adults have grown up in an electronic age. According to the National Sleep Foundation's 2006 Sleep in America Poll, almost all adolescents had at least 1 media electronic device in their bedroom.⁴ Among the devices reported were televisions (57%), music players (90%), video game consoles (43%), computers (28%), and phones (64%). A more rigorous study of subjects recruited from a pediatric office in a Philadelphia suburb showed that of the 100 adolescents ranging in age from 12 to 18 years, two-thirds had a television in their bedroom, almost one-third had a computer, almost 80% had a digital music player, and 90% had a cellular phone in their bedroom.⁴² The teenagers engaged simultaneously

in an average of 4 electronic activities after 9:00 PM.

It is not surprising that several studies in adolescents have demonstrated that electronic exposure in the evening potentially disrupts sleep. The use of multiple electronic devices at the same time has been associated with less sleep at night and a greater degree of sleepiness during the daytime.^{4,15,31,42,43} Having a television in the bedroom (or even out of the bedroom) has been associated with later bedtimes on weekdays, longer sleep latencies, shorter total sleep times, later wakeup times on the weekends, and more daytime sleepiness in adolescents.^{44–46} In the Children in the Community Study in 1976,⁴⁷ adolescents who were watching 3 or more hours of television not only experienced difficulty falling asleep and frequent awakenings but also had a risk of having difficulties with their sleep later in adolescence and young adulthood. The use of computers before bedtime has also been shown to have the same effect, and this finding has been demonstrated in a wide range of countries and cultures.^{45,46,48–51}

Engaging in a greater number and range of sleep-interfering activities before going to bed has also been associated with less nocturnal sleep and more daytime sleepiness in adolescents.⁴⁵ Several mechanisms have been postulated about how media disrupts sleep.⁴⁰ One is that the use of media directly displaces sleep; an adolescent or young adult may simply stay up later enjoying whatever media he or she is using. In addition, electronic media allow for greater interaction between friends. Early data suggested that peer-to-peer interaction did not have a major influence on school-night bedtime but rather had a more significant influence on a teenager's sleep on weekends.⁵² These findings may no

longer hold now that there are enhanced ways for adolescents to communicate electronically. Calamaro et al⁴² found that after 9:00 PM, 34% of adolescents in the study sample were text messaging, 44% were talking on the phone, 55% were online, and 24% were playing computer games. In another study of Belgian teenagers, 62% of the subjects used their phones after the lights were turned off, and phone use at this time was associated with increased daytime tiredness the next day.⁵³

Another possible mechanism for the detrimental effect of electronics use on sleep is that the light produced by electronic devices may disrupt circadian rhythms by suppressing melatonin, resulting in the inability to fall asleep at a reasonable time.⁴⁰ Recent studies have demonstrated that exposure to relatively low-intensity light can alter circadian rhythms^{54,55} and suppress nocturnal melatonin secretion.⁵⁶

Finally, media use may cause increased sleep-disrupting mental, emotional, and physiologic arousal.⁴⁰ One study found that subjective sleepiness was lower, sleep latency was longer, and rapid eye movement (REM) sleep was shorter in subjects after playing video shooting games, independent of the brightness of the screen used.⁵⁶ Another study that compared playing an interactive computer game with watching a movie on television in the evening⁵¹ found a decline in verbal memory performance, prolonged sleep latency, and an increase in light sleep in the computer game cohort.

School Start Times

As has been described elsewhere in the present report, a multitude of changes occur over the course of adolescence that can affect the quality and quantity of sleep in adolescents and young adults. One of the most salient and arguably most malleable is that of school start times, a systemic

countermeasure. There are clearly a number of practical implications and/or challenges that schools might face when considering altering school start times, such as changes in athletic schedules, effects on after-school activities, and transportation issues.⁵⁷ Despite these hurdles, a small yet increasing number of school districts over the last 15 years have responded to research reports regarding the prevalence of inadequate sleep among middle and high school students by delaying school start times. Research on the effects of delaying the start times of middle and high schools for adolescents' sleep and daytime functioning is discussed in this section, and a more detailed discussion is available in the American Academy of Pediatrics policy statement on school start times.⁵⁸

In one of the first studies to assess the effect of school start times on adolescents,⁵⁹ a 65-minute earlier school start time in the transition from grade 9 to grade 10 resulted in fewer than one-half of 10th graders obtaining an average of 7 hours or more of sleep on school nights and physiologic levels of daytime sleepiness ordinarily seen in patients with narcolepsy. A large prospective longitudinal study of delays in school start times in both an urban and a suburban school district found improvements in attendance rates and an increase in the percentage of high school students continuously enrolled in the district or the same school, although grades did not show a statistically significant improvement.⁶⁰ Similar to what has been reported in subsequent studies,⁵⁵ bedtimes did not change with the delay in start times, but morning wake times were significantly later, resulting in the students obtaining nearly 1 hour more of sleep on school nights. Other studies have also reported increases in sleep duration

and decreased daytime sleepiness associated with delayed school start times,⁶¹ as well as increased satisfaction with sleep and motivation and significant declines in self-reported depressed mood, health center visits for fatigue-related complaints, and first-period tardiness.⁶²

Research on the effects of early versus delayed school start times for young adolescents has resulted in strikingly similar findings. Students at later-starting middle schools report later rise times, more total sleep on school nights, less daytime sleepiness, less tardiness, fewer attention/concentration difficulties, and better academic performance compared with middle school students at earlier-starting schools.^{63,64} In addition, middle school students with a delayed start time of 1 hour for just 1 week performed better than the earlier-starting comparison group on tests requiring attention.⁶⁵ Undoubtedly, delaying the start of middle school allows early adolescents, similar to their older high school-aged peers, to obtain sufficient sleep and to perform better in school.

Danner and Phillips⁵³ demonstrated that delaying school start times in 1 community in Kentucky decreased the average crash rate for teenaged drivers by 16.5%, while the state as a whole increased by 7.8% in the same time period. In another recent study conducted in 2 adjacent, demographically similar cities, there were significantly increased teenaged (16- to 18-year-olds) crash rates over a 2-year period in the city with earlier high school start times.⁶⁶

Taken together, it is clear that when middle and high schools (schools designed for adolescents) institute the countermeasure of delaying the start time of school, students obtain more sleep and there are associated improvements in behaviors pertinent to academic success (attendance and school performance) and safety.

Caffeine

Use of caffeine has been understudied in adolescents and children; however, current research has raised important questions regarding the complex interrelationship between caffeine use and sleep patterns during this developmental period.^{67–70}

Similar to studies of adult caffeine use, higher caffeine intake as early as 12 years of age is associated with shorter sleep duration, increased sleep onset latency, increased wake time after sleep onset, and increased daytime sleepiness.^{68,69,71} High school students who report a moderate to high intake of caffeine versus very low intake were nearly 2 times more likely to have difficulty sleeping and to report morning sleepiness.⁷¹ High and regular caffeine users seem to develop a cycle in which disrupted sleep attributable to caffeine use leads to sleepiness, which then leads them to increase their caffeine consumption.⁷² Moreover, caffeine reduces the percentage of time spent in slow-wave or “deep” sleep in a dose-related manner and alters the temporal organization of REM/non-REM sleep.^{70,72,73} This outcome is particularly important because of the critical role that both slow-wave sleep and REM sleep play in learning and memory consolidation.

Researchers are beginning to examine adolescents’ expectancies regarding caffeine use. Reported expectancies for caffeine users were for energy and mood enhancement and to counteract the effects of sleep disturbances. Other studies have found that adolescents report using energy drinks for the energy boost or “buzz” and that these beverages make them “feel more energetic.”⁷⁴ In comparing different types of users, “mixed” caffeine product users (ie, soda, coffee, energy drinks) reported higher levels of withdrawal and/or dependence, energy and mood enhancement, appetite suppression, and performance enhancement expectancies

than either the high-soda or low-caffeine use groups. A higher percentage of mixed users compared with high-soda users reported that the reasons for their caffeine use were related to getting through the day, experimentation, and recreation.⁶⁸

Regardless of the reasons adolescents use caffeinated substances, there are clear consequences. Adolescents experience tolerance and withdrawal symptoms; however, in general, caffeine dependence in adolescents is poorly understood.^{75,76} Female high school students were more likely to report withdrawal/dependence caffeine expectancies as well as appetite suppression expectancies compared with their male peers.⁶⁸ Although adolescents may consume excessive caffeine in an attempt to mitigate daytime sleepiness, this action not only further compromises the quality and quantity of sleep, but high caffeine users may also be at risk for other substance use and/or abuse as well as other risk-taking behaviors.^{68,75,77–79} Consumption of caffeine is linked to nicotine use in adolescents,⁸⁰ which in turn may further disrupt sleep⁸¹ and perpetuate the cycle of sleep fragmentation/daytime sleepiness coupled with stimulant use. Not surprisingly, increased caffeine use frequently coexists with other behaviors that negatively affect sleep, such as adolescents’ late-night, multifaceted technology use. For example, a recent study⁴² found that high school-aged adolescents who reported the highest levels of multitasking with media-related electronic products also consumed the most caffeine.

The correlation between caffeine consumption and daytime sleepiness is, in turn, inversely correlated with academic achievement. For example, 1 study of over 7000 adolescents reported that a significant proportion of the variance that occurs in academic achievement

was found to be attributable to caffeine use.⁸² The authors further postulated that daytime sleepiness might be an important mediator of the negative impact of not only caffeine but also alcohol use and cigarette smoking on academic success. Caffeine use may also serve as an affect modulator, particularly when it comes to adolescents with excessive daytime sleepiness or insufficient sleep. For example, studies have suggested that adolescents may use caffeine as a means of regulating mood and/or helping to alleviate depression.^{75,83}

Undoubtedly, there is growing evidence that caffeine use is increasing among adolescents, with negative implications for sleep and other behaviors. Significant questions, however, remain regarding the direction of this complex relationship. Are adolescents turning to caffeine because of insufficient and inconsistent sleep patterns, or does increased caffeine use exacerbate sleep problems for developing adolescents? These findings document the need for more extensive health education about caffeine use during adolescence. Furthermore, with the dramatic and potentially dangerous rise in the consumption of energy drinks in combination with alcohol (particularly on college campuses), researchers and physicians need to carefully investigate the implications for adolescents across the developmental spectrum.⁸⁴

Other Factors Affecting Sleep in Adolescents

A number of other factors have been related to reduced sleep durations across the adolescent age range, such as chronic medical illnesses, mental health issues (ie, anxiety/stress), and prescribed psychotropic medications.^{10,15} Chronic respiratory illnesses, such as asthma, and pain conditions, such as migraines, may contribute to truncated and disrupted sleep. Although obesity

does not necessarily lead to poor sleep per se, it is an increasingly important risk factor for obstructive sleep apnea in adolescents, which in turn results in poor-quality sleep and daytime consequences. Moreover, although the evidence is still largely anecdotal, the use of stimulants (particularly those typically prescribed for the treatment of attention-deficit/hyperactivity disorder) as a “countermeasure” to sleepiness and/or as academic “performance enhancers” seems to be an increasingly common phenomenon across college campuses.^{85,86} Future investigations need to assess the extent and context of “diversion” of legitimately prescribed stimulant medications as well as the use and abuse of increasingly diverse alternative sources of caffeine (eg, caffeinated alcoholic beverages, candy, foodstuffs). Finally, it should also be noted that both over-the-counter (ie, diphenhydramine) and prescription (ie, zolpidem) medications taken by adolescents to induce sleep may result in residual daytime sleepiness and that commonly used medications (eg, decongestants) and prescription drugs (eg, activating antidepressants [eg, fluoxetine], stimulant medication for attention-deficit/hyperactivity disorder) may also result in disrupted sleep and consequent daytime sleepiness in adolescents.

CONSEQUENCES OF INSUFFICIENT SLEEP

It is important to recognize that the causes and consequences of chronic sleep loss in adolescents are often closely intertwined in complex ways, further exacerbating the situation. For example, alcohol consumption can lead to insufficient and poor-quality sleep and subsequent daytime sleepiness.^{10,32,87} In turn, chronic sleep loss has been linked to an increased risk of alcohol and drug use.^{14,28,34} Similarly, compensatory oversleep behavior on weekends provides some temporary relief from sleepiness generated by insufficient

sleep on weekdays, but it also leads to disrupted sleep–wake cycles, exacerbation of the normal adolescent circadian phase delay, and perpetuation of compromised weekday alertness. Moreover, consequences such as poor judgment, lack of motivation, and inattention and affective dysregulation resulting from sleep loss, as well as the effect of insufficient sleep on decision-making skills,⁸⁸ further compound the potential negative effects in adolescents. In particular, higher level cognitive “executive functions,” for which adolescence is a critical period of evolution, are selectively affected by sleep loss.⁸⁹

Sleep Loss and Depression, Mood Disturbances, and Suicidal Ideation

It has long been recognized that mood disorders (especially major depressive disorder) in clinical samples of adults exhibit a bidirectional relationship with sleep disturbances, and the presence of sleep problems has been shown to both increase the relative risk of developing depression⁹⁰ and to be a predictor of relapse.^{91,92} Similar findings have emerged in the child and adolescent population, particularly with regard to an association between insomnia (difficulty initiating and/or maintaining sleep) and clinically diagnosed depression.⁹³ Recent studies have shown that addressing insomnia will greatly improve treatment of depression. Although studies examining sleep architecture in depressed adolescents⁹⁴ have not consistently replicated differences in polysomnographic findings in depressed adults (ie, increased REM sleep, decreased REM onset latency), there may be other sleep electroencephalographic markers, such as sleep spindle activity and cyclic alternating patterns,⁹⁵ that have more relevance for the adolescent population.

Sleep debt in college students has been shown to be associated with

a higher risk of reporting depressive symptoms.⁹⁶ Similarly, in high school students, shorter school-night total sleep time has been associated with both daytime sleepiness and depressive symptoms,⁹⁷ whereas increased risk-taking behaviors were associated with irregular sleep patterns and self-reported sleep problems rather than sleep loss. These outcomes are similar to the findings of a large longitudinal adolescent health study in which symptoms of possible insomnia (ie, trouble sleeping, morning tiredness) predicted risk behaviors (eg, drinking and driving, smoking, delinquency) after controlling for depression symptoms.^{97,98}

There is evidence that other sleep-related parameters may also have a significant effect on mood; for example, adolescent self-reported sleep variables (including trouble sleeping, tiredness, nightmares, and being a long sleeper) have been found to be significantly associated with psychological symptoms, including anxiety/depression, and withdrawal.⁹⁹ Circadian factors may also play a role in mood regulation; increased self-reported “eveningness,” a marker of circadian phase delay, has also been associated with depression and lower behavior activation/positive affect.¹⁰⁰

A number of recent studies have focused on the possible relationship between sleep and suicidal ideation.^{101,102} Sleeping less than 8 hours at night seems to be associated with an almost threefold increased risk of suicide attempts after controlling for a number of confounding variables.¹⁰¹ Not only do adolescents with insufficient sleep have an increased risk of suicidal ideation, but the risk may be similarly increased in adolescents whose parents also have insufficient sleep, raising some interesting questions about multigenerational environmental and/or genetic factors.¹⁰³ A

similar relationship has been found in middle and high school students; adolescents with parental-set bedtimes of midnight or later are significantly more likely to suffer from depression and to have suicidal ideation compared with adolescents with parental-set bedtimes of 10:00 PM or earlier. Earlier parental-set bedtimes, therefore, could potentially be protective against adolescent depression and suicidal ideation. Finally, both decreased (≤ 5 hours) or increased (≥ 10 hours) total sleep times may put adolescents at a significantly higher risk of suicidality compared with a total sleep time of 8 hours.¹⁰⁴ However, increased risk of the most severe forms of suicidality (attempt requiring treatment) seems to be associated with significantly shorter sleep duration (total sleep time ≤ 4 hours).

In summary, sleep has an important influence on mood and the development of depressive symptoms in adolescents. Although insufficient sleep and daytime sleepiness seem to have the most robust relationship with mood dysregulation, poor-quality sleep and irregular sleep patterns are also associated with depressed mood. Importantly, from a clinical standpoint, improvements in sleep may lead to improvements in mental health functioning (and vice versa). The association between sleep loss and increased suicidality in adolescents is particularly troubling and is clearly important for pediatricians to recognize.

Insufficient Sleep and Obesity Risk

A considerable body of evidence now links short sleep duration in both adults and children with an increased risk of obesity, an association that obviously has long-range health implications. With regard to mechanisms, experimental studies of sleep restriction in healthy adult volunteers have shown that there are alterations in

metabolic profiles (eg, insulin, ghrelin, leptin, cortisol) associated with sleep loss, which result in insulin resistance, increased sympathetic nervous system activity, and increased hunger and decreased satiety.¹⁰⁵ As a result, sleep-restricted subjects consume more calories, exercise less, and consume a higher percentage of calories from fat.^{106–109}

In 1 earlier study, it was estimated that for each hour sleep lost, the odds of being obese increased in adolescents by 80%.¹¹⁰ Furthermore, there is evidence of a “dose–response” inverse relationship between sleep and weight,¹¹¹ with odds ratios of overweight increasing with decreasing sleep duration (< 5 hours, 5–6 hours, 6–7 hours, and 7–8 hours compared with students sleeping > 8 hours). The increased risk of obesity associated with insufficient sleep seems to be equivalent to or higher than the risk associated with other factors strongly correlated with weight, such as parental obesity and television viewing.¹¹²

Early sleep patterns may influence BMI in adolescents and young adults as well. Longitudinal data suggest that children who sleep less, have later bedtimes, or get up earlier subsequently have higher BMIs and are more likely to be overweight, even after controlling for baseline BMI.¹¹³ This association may be established early in life; for example, an increased BMI and high prevalence of obesity in young adults was found in individuals whose mothers had reported sleeping problems (“irregular” or “troubled” sleeping) at ages 2 to 4 years (although sleep duration was not specified) compared with those who had not had sleeping problems.¹¹⁴

Although the underlying potential mechanisms for the relationship between sleep and weight in adolescents have yet to be elucidated, metabolic alterations associated with sleep loss similar to those observed in adults are

likely to play an important role. In particular, perturbations in the levels of neurohormones known to be associated with hunger and satiety (eg, adiponectin, ghrelin) as well as increased insulin resistance (as measured by the homeostatic model assessment [HOMA]) have been demonstrated in adolescents sleeping < 5 hours per day.¹¹⁵ These “short sleepers” were also found to have a higher percentage of carbohydrate intake according to a dietary questionnaire.¹¹⁶ Similarly, older adolescents sleeping less than 8 hours have been shown to consume a higher proportion of calories from fats, and shorter sleep duration is also associated with increased odds of consuming a higher percentage of daily caloric intake from snacks.¹¹⁷ Importantly, these metabolic perturbations also increase the risk of development of type 2 diabetes in these obese adolescents.^{118,119} Finally, it should be noted that the relationship between short sleep duration and obesity may be further complicated by the presence of obstructive sleep apnea. Not only is obesity emerging as an increasingly important risk factor for sleep-disordered breathing in children,¹²⁰ but obstructive sleep apnea may further exacerbate the inflammatory and metabolic consequences of both obesity and chronic sleep loss.^{7,121–123} Some evidence also suggests there may be gender differences in the strength of the association between obesity and sleep duration, with adolescent boys seeming to be at higher risk compared with girls in both cross-sectional and longitudinal studies using large data sets.¹²⁴ However, not all studies have identified gender differences; in 1 study of junior high school students, short sleep duration was significantly associated with overweight in girls only.¹²⁵

Finally, it should be noted that not all studies have found an inverse

relationship between sleep duration and obesity in adolescents.¹²⁶ It has been postulated that some of these discrepancies may be attributable to measurement issues; in a nationally representative sample of adolescents that included 2 different measures of sleep duration (24-hour time diaries and self-reported “usual” sleep hours), self-reported sleep duration and time-diary sleep were only weakly correlated with each other, and only self-reported sleep hours were inversely associated with overweight.¹²⁷

In summary, despite a number of methodologic limitations, the body of evidence from studies assessing the relationship between short sleep and increased overweight/obesity risk in adolescents is both compelling and potentially far-reaching in its public health implications. More research is urgently needed to identify specific metabolic, inflammatory, and hormonal mechanisms as well as the interactions among sleepiness and activity levels, mood, cognition, and behavioral responses in this complex equation. Moving forward, both community-based obesity prevention programs, such as “Let’s Move” (<http://www.letsmove.gov>), and clinical treatment programs for overweight and obese teenagers should include consideration of sleep as an important variable in the relative success or failure of these interventions.

Drowsy Driving in Adolescents

It is now well recognized that daytime sleepiness and fatigue are associated with an increased rate of motor vehicle crashes.^{128–131} The fact that sleepiness could be a major factor in individuals without known sleep disorders was not universally accepted until the landmark paper¹³² by Pack et al in 1995. This group reviewed crash

reports from the state of North Carolina between 1990 and 1992 in which the driver was judged to have fallen asleep behind the wheel. In the 85% of crashes in which intoxication was not thought to be a contributing factor, the majority (55%) occurred in individuals 25 years or younger. Crashes in this younger age range generally occur at night, unlike crashes with older adults, which typically occur during the mid-afternoon,^{133,134} and tend to occur predominantly when the drowsy driver is alone.^{135–137} In addition, young male drivers are more likely to be involved in sleep-related crashes than are young female drivers.^{132,134,136}

Sleepiness while driving is a common complaint among adolescents¹³⁶ and college students.¹³⁷ In a study of high school students with driver’s licenses, one-fifth reported poor-quality sleep, almost two-thirds complained of daytime sleepiness, 40% reported having sleepiness while driving, and 11% reported having had an automobile crash in which sleepiness was the main cause. Being sleepy behind the wheel and poor-quality sleep at night also seem to increase the risk of having an automobile crash in college students.

Countermeasures may potentially help prevent traffic accidents in this age range. Avoidance of driving when sleep deprived and not drinking alcohol before getting behind the wheel are obvious solutions. Other countermeasures that have some empiric support in adults and may be effective in adolescents include planned napping.^{138,139}

CONCLUSIONS

Adolescent sleep loss poses a serious risk to the physical and emotional health, academic success, and safety of our nation’s youth. The prevalence and effects of insufficient sleep may

be further magnified in high-risk adolescents. Pediatricians have the opportunity to make significant inroads into addressing the health risk that sleep loss presents through screening and health education efforts. Many of the factors that have been shown to contribute significantly to the current “epidemic” of insufficient sleep in teenagers, such as electronic media use, caffeine consumption, and early school start times, are potentially modifiable and, as such, are important intervention points in anticipatory guidance in the clinical setting. On the local and national levels, pediatricians need to advocate for educational, administrative, and health policies that promote healthy sleep and reduce the risk factors for sleep loss in adolescents.

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Interferon- γ Release Assays for Diagnosis of Tuberculosis Infection and Disease in Children

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- *Technical Report*

TECHNICAL REPORT

Interferon- γ Release Assays for Diagnosis of Tuberculosis Infection and Disease in Children

Jeffrey R. Starke, MD, FAAP and COMMITTEE ON INFECTIOUS DISEASES

KEY WORDS

bacille Calmette-Guérin, interferon- γ release assay, tuberculin skin test, tuberculosis

ABBREVIATIONS

BCG—bacille Calmette-Guérin
 ELISA—enzyme-linked immunosorbent assay
 ELISPOT—enzyme-linked immunosorbent spot
 IGRA—interferon- γ release assay
 INF- γ —interferon- γ
 LTBI—latent tuberculosis infection
 NTM—nontuberculous mycobacteria
 PPD—purified protein derivative
 QFT—QuantIFERON-TB Gold In-Tube assay
 TB—tuberculosis
 T-SPOT—T-SPOT.TB assay
 TST—tuberculin skin test

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abstract

FREE

Tuberculosis (TB) remains an important problem among children in the United States and throughout the world. Although diagnosis and treatment of infection with *Mycobacterium tuberculosis* (also referred to as latent tuberculosis infection [LTBI] or TB infection) remain the lynchpins of TB prevention, there is no diagnostic reference standard for LTBI. The tuberculin skin test (TST) has many limitations, including difficulty in administration and interpretation, the need for a return visit by the patient, and false-positive results caused by significant cross-reaction with *Mycobacterium bovis*-bacille Calmette-Guérin (BCG) vaccines and many nontuberculous mycobacteria. Interferon- γ release assays (IGRAs) are blood tests that measure ex vivo T-lymphocyte release of interferon- γ after stimulation by antigens specific for *M tuberculosis*. Because these antigens are not found on *M bovis*-BCG or most nontuberculous mycobacteria, IGRAs are more specific tests than the TST, yielding fewer false-positive results. However, IGRAs have little advantage over the TST in sensitivity, and both methods have reduced sensitivity in immunocompromised children, including children with severe TB disease. Both methods have a higher positive predictive value when applied to children with risk factors for LTBI. Unfortunately, neither method distinguishes between TB infection and TB disease. The objective of this technical report is to review what IGRAs are most useful for: (1) increasing test specificity in children who have received a BCG vaccine and may have a false-positive TST result; (2) using with the TST to increase sensitivity for finding LTBI in patients at high risk of developing progression from LTBI to disease; and (3) helping to diagnose TB disease. *Pediatrics* 2014;134:e1763–e1773

INTRODUCTION

Tuberculosis (TB) remains an important disease in the United States and throughout the world. Of the almost 9 million annual cases of TB globally, approximately 10 000 cases occur in the United States.¹ Of the 2660 children and adolescents younger than 18 years with TB disease reported in the United States from 2008 to 2010, 31% were born in other countries.² Among the US-born pediatric patients, 66% had at least 1 foreign-born parent, and 75% of all the pediatric patients had some international connection through family or residence history. Although 52% of these cases occurred in children ages 13 to 17 years,

infants and young children have the highest rate of TB infection progressing to TB disease rapidly after exposure (ie, within a few weeks to several months). Children who immigrated to the United States from countries with high TB burden often received no testing for latent tuberculosis infection (LTBI), expanding the pool of infected children in the United States. Some of these children developed TB disease or were evaluated and treated for LTBI after immigration, but many have untreated LTBI and are at risk for developing TB disease later in life. In addition, many US-born children who have been infected with *Mycobacterium tuberculosis* within the United States or abroad have gone undetected.

In most children and adolescents, initial infection with *M tuberculosis* is eliminated or contained by host defenses, the infection becomes “latent,” and the person remains asymptomatic. However, latent bacilli may remain viable and become active again to cause TB disease. Treatment of LTBI substantially reduces the risk of developing TB disease in both the immediate and distant future.³ Therefore, the goal of testing for LTBI is to identify those individuals who are at increased risk of developing TB disease and will benefit the most from treatment. In the pediatric population, infants and very young children and adolescents are at higher risk of progressing to TB disease than are primary school-aged children. The risk of progression in infants younger than 12 months is 40%; it is decreased to 25% in children 1 to 2 years of age and is 10% to 15% in older children and adolescents. Epidemiologic factors also define risk: children who were born and lived in or have traveled to an area of the world with a high prevalence of TB and those who have had a household or family member with TB disease or LTBI are at higher risk for LTBI than the general population. As

a result, selective testing for LTBI of children on the basis of their risk factors has been adopted as the main strategy in the United States.

Although the diagnosis of TB disease is confirmed by the detection of *M tuberculosis* in a clinical sample, there is no diagnostic gold standard for the diagnosis of LTBI.³ Two available but imperfect methods for identification of LTBI are the tuberculin skin test (TST) and interferon- γ release assays (IGRAs). Both methods depend on cell-mediated immunity and provide immunologic evidence of host sensitization to antigens of *M tuberculosis*. Neither method can distinguish between LTBI and TB disease, and both methods display suboptimal performance in immunocompromised patients, who are at greatest risk for progression of TB infection to TB disease. The objective of this technical report is to review the current evidence for the best uses of IGRAs in children.

TUBERCULIN SKIN TESTS

The TST was first developed by Charles Mantoux in 1907 and has been an important factor in the decline of TB disease in much of the Western world. It has existed in several forms, currently the Mantoux test, which is the intradermal injection of 5 TU of purified protein derivative (PPD) or 2 TU of PPD-RT23. PPD tuberculin solution contains dozens of TB antigens, with the exact composition varying among batches and preparations. Many of these antigens are also present in environmental nontuberculous mycobacteria (NTM) prevalent throughout the United States. A patient who mounts a cell-mediated response to tuberculin antigens has a delayed-type hypersensitivity response usually within 48 to 72 hours, causing measureable induration at the injection site.

TST results can be difficult to interpret. The test depends on accurate

intradermal injection and should be performed by an experienced individual. Interpretation requires that the family return in 48 to 72 hours. Correct interpretation of the reaction involves careful measurement of the induration determined by a provider with clinical experience in this measurement. The measurement should be recorded to the nearest millimeter of the transverse diameter of the induration. The variation in the reaction size of an individual host, determined by placement of the test simultaneously on both arms, averages 15%; the variability in measuring induration among experienced observers also varies by approximately 15% and is much greater among inexperienced personnel and untrained people, such as family members.^{4,5} Therefore, family members should not be allowed to interpret a TST result. False-negative TST results can be caused by improper handling of the PPD solution, improper placement of the test, incorrect interpretation of the results, or advanced TB disease.

Induration at the site of the TST is caused by migration of mostly mononuclear cells to the area and the inflammatory process secondary to the response of these cells. This response can be attributable to infection with *M tuberculosis*, exposure to NTM, or receipt of bacille Calmette-Guérin (BCG) vaccine.⁶ The TST cannot distinguish between TB infection and TB disease. The patient's history and the size of the induration help to determine, to some degree, which of the 3 potential causes is correct. Subjects with exposure to environmental NTM typically have indurations <10 mm, but larger reactions are not uncommon. Among populations with a low prevalence of TB but a high prevalence of exposure to environmental NTM, such as in the United States, the distribution of reactions among subjects with LTBI and those with NTM exposure will overlap

to some degree. The most effective way to minimize false-positive results is to avoid testing subjects who lack a risk factor for LTBI. When testing is performed, the recommendation has been to vary the cutoff for the size of the TST reaction considered positive. The cutoff is set at 15 mm to optimize specificity for subjects lacking LTBI risk factors, 10 mm for subjects with a risk factor for LTBI, and 5 mm to optimize sensitivity for subjects at high risk of having or developing TB disease if they have LTBI (clinical evidence of disease, recent exposure, or significant immune compromise).⁷

BCG vaccines are administered in countries with high TB burden because these vaccines reduce the risk of TB disease, particularly disseminated (miliary) and central nervous system TB. For a foreign-born child, history of BCG vaccination should be determined by examination of the vaccination record and looking for a typical BCG scar, which is usually found on the deltoid region of either arm. Some of the antigens in PPD are also found in *M bovis*-BCG, the organism in the BCG vaccines. Some subjects who are not infected with *M tuberculosis* express induration in response to the TST that reflects previous receipt of a BCG vaccination. The size of the TST reaction varies with the strain and dose of vaccine,⁸ the route of administration,⁹ age at vaccination,¹⁰ the time interval since vaccination,¹¹ and the number of BCG doses. Approximately one-half of infants who received a BCG vaccination will respond with significant induration to a TST. Although most (perhaps as many as 90%) children 5 years or older who received a BCG vaccine as an infant will not have a positive response to a TST (unless also infected with *M tuberculosis*, which may not be prevented by BCG), some will retain this response, causing a false-positive result. The induration often measures

<10 mm but can be >15 mm. Children born in most foreign countries are candidates for selective testing for LTBI, but a large number of false-positive results can occur when the TST is used on children who have received a BCG vaccine. Children who have received a BCG vaccination may also be subject to boosting by the TST (ie, the immunologic recall of hypersensitivity to antigens in the PPD that are also present on *M bovis*-BCG), which creates a false-positive TST result on repeat testing.^{12,13}

False-negative TST results can occur because of the limited ability of certain children with LTBI or TB disease to mount an appropriate delayed-type sensitivity response, especially those who are immunosuppressed either by disease (eg, advanced HIV infection, advanced TB, cancer, malnutrition) or those who have received immunosuppressive treatments (eg, corticosteroids, cancer chemotherapy, immunomodulating biologic agents [especially the tumor necrosis factor α inhibitors], or live viral vaccines [particularly measles vaccine]). Unfortunately, children for whom the TST has diminished sensitivity are those subjects most likely to progress to TB disease if infected.³

In summary, there are limitations to both the sensitivity and the specificity of the TST.¹⁴ The positive predictive value of the TST is much greater when it is applied to subjects who have a recognized risk factor for LTBI. When the TST is used in subjects lacking risk factors, the vast majority of the positive results are falsely positive, and this problem is accentuated in children who received a BCG vaccine.

INTERFERON- γ RELEASE ASSAYS

IGRAs are ex vivo blood tests that detect interferon- γ (INF- γ) release from a patient's CD4+ T lymphocytes after stimulation by antigens found on the *M tuberculosis* complex (which includes

M bovis, *Mycobacterium africanum*, *Mycobacterium microti*, and *Mycobacterium canettii*). Two IGRAs are available commercially: the QuantiFERON-TB Gold In-Tube assay (QFT; Cellestis/Qiagen, Carnegie, Australia) and the T-SPOT.TB assay (T-SPOT; Oxford Immunotec, Abingdon, United Kingdom). Both tests use early secreted antigenic target 6 and culture filter protein 10 encoded by genes located within the region of difference 1 locus of the *M tuberculosis* genome.¹⁵ The QFT uses a third antigen (TB7.7). The region of difference 1 antigens used in the 2 IGRAs are not encoded in the genomes of *M bovis*-BCG strains (although they are present on wild-type *M bovis*) or most species of NTM, specifically not on the *Mycobacterium avium* complex organisms that are the most ubiquitous pathogenic environmental NTMs. (The antigens are found on several NTM strains, including *Mycobacterium marinum*, *Mycobacterium kansasii*, *Mycobacterium szulgai*, and *Mycobacterium flavescens*.) As a result, one would expect that these tests would be more specific than the TST, yielding fewer false-positive results. Unfortunately, as with the TST, the IGRAs do not distinguish between TB infection and TB disease.

Test Characteristics

Both IGRAs are performed with positive and negative controls. The QFT assay is an enzyme-linked immunosorbent assay (ELISA) whole blood test. The result is reported as quantification of INF- γ in international units per milliliter. The test result is considered positive when the INF- γ response to the TB antigen is above the test cutoff of 0.35 IU (after subtracting the negative control value from the test antigen value). If the test result is negative, but the positive control also shows a poor response or the background response in the negative control is too high, the result is considered indeterminate (ie, neither

negative nor positive). The T-SPOT assay is an enzyme-linked immunosorbent spot (ELISPOT) assay performed on peripheral blood mononuclear cells that have been incubated with the 2 antigens. The result is reported as the number of INF- γ -producing T cells (spot-forming cells). The test result is considered positive when the number of spots in the test sample, after subtracting the number of spots in the negative control, exceeds a specific threshold (usually 8 spots). Results with a corrected spot count of 5, 6, or 7 are considered borderline (equivocal), and retesting on a different specimen is recommended by the manufacturer. If the test result is negative but the positive control also shows a poor response or if the background response in the negative control is too high, the result is termed invalid (sometimes also called indeterminate [neither negative nor positive]).

Although there are standard manufacturer instructions for performing the IGRAs, concerns have been raised about the reproducibility of the results on serial performance.^{16,17} Serial testing of health care workers at low risk of infection has often revealed unexplained conversion of IGRA results to positive and reversion to negative. Nkurunungi et al¹⁸ performed T-SPOT tests on 405 Ugandan children at age 5 years and then repeated the test 3 weeks later. Of 79 children who had an initial positive T-SPOT result, only 30 (38%) had a positive result 3 weeks later, whereas 96% of the children with an initial negative result had a negative result on repeat testing. The test agreement was better among children who were household contacts of a TB case ($\kappa = 0.77$) than among noncontacts ($\kappa = 0.29$). T-lymphocyte assays are susceptible to variability by numerous factors, including³: manufacturing issues; sample collection issues, such as inconsistencies in specimen collection, inadequate

blood volume, delays in isolation and incubation of cells, and inadequate shaking (mixing) of the QFT collection tubes; laboratory issues caused by systematic or random error; and immunologic sources, including possible boosting of the response by a recently performed TST.¹⁶ Published studies have shown a variety of differences in outcomes between the 2 basic IGRA techniques, ELISA (QFT) and ELISPOT (T-SPOT). However, in most studies, these differences have been small, and the preponderance of evidence supports the conclusion that, in terms of accuracy, neither IGRA test is preferred over the other.

Summary of Studies in Adults

As with most new diagnostic tests, the early studies were conducted on adults. Because there is no reference standard test for LTBI, specificity was estimated among low-risk subjects with no known TB exposure in a low-prevalence setting. Several meta-analyses of studies in adults have demonstrated an IGRA specificity of 95% to 100%, and, as expected, the specificity is not affected by previous BCG vaccination.^{19–21} Although TST specificity is comparable to IGRAs in adults who have not received a BCG vaccine, it is substantially lower (approximately 60%) and variable among BCG-vaccinated populations.³ In contact investigations of adults with pulmonary TB, measures of exposure have often correlated better with IGRA-positive results than with the TST because of more positive TST results in subjects with low intensity of exposure, especially within BCG-vaccinated populations.^{22,23} Test sensitivity is estimated initially among culture-confirmed cases of disease (absolute proof of infection). The sensitivity of the IGRAs in adults with culture-proven TB disease is 80% to 90% (compared with 80% for the TST). As with the TST, the IGRA sensitivity is lower in adults who are immunocompromised, especially those with

poorly suppressed concomitant HIV infection.

General Aspects of Studies in Children

Determining the sensitivity and specificity of the IGRAs for children is more difficult, and fewer studies have been published.²⁴ Most children with clinical TB disease do not have microbiologic confirmation, which means they lack the absolute proof of infection that is needed to accurately assess test sensitivity; many studies have used less reliable methods of clinical diagnosis of TB disease instead. The major difficulty for interpreting studies of LTBI is determining for discordant test results whether the negative test result is more specific or the positive test result is more sensitive. Gradients of exposure to a culture-positive case are frequently used to determine the meaning of discordant results. Four systematic reviews and meta-analyses of the available studies of the use of IGRAs in children were published in 2011 and 2012; as expected, these reviews examined many of the same studies.^{25–28} Analysis of the studies was hampered by the heterogeneous methods used, including varying definitions of a clinical case of TB disease. Studies have been performed in countries with both low and high TB burden, which often differ greatly in the severity of TB disease, rates of malnutrition in children, availability of TB diagnostic tools, structures of households where transmission often occurs, and the use of various BCG strains and vaccination techniques. Some of the published studies used ELISA and ELISPOT techniques that were different from those that are currently available commercially.

Test Specificity in Children

Although there are variable results among individual published studies,

the strongest and most consistent finding is that the IGRAs have a higher specificity for LTBI, especially in settings of low TB burden and for BCG-vaccinated children. This conclusion is based largely on comparison of test results across exposure gradients of contact investigations in schools and the community in otherwise low-burden settings.^{22,29,30} In their meta-analysis, Sun et al²⁷ included 7 studies that assessed IGRA specificity in populations with rates of BCG vaccination ranging from 0% to 100%. The pooled specificity was 100% for ELISA studies, 90% for ELISPOT studies, and 56% for TST. The specificity of ELISPOT was 89% for BCG-vaccinated children and 95% for BCG-unvaccinated children, compared with a TST specificity of 49% for BCG-vaccinated children and 93% for BCG-unvaccinated children. Five of the 7 studies concluded that agreement (measured by using κ scores) between the TST and IGRA results in BCG-unvaccinated children was higher than in vaccinated children, probably because of false-positive TST results caused by previous BCG vaccination. Lighter et al³⁰ found that among 207 children in New York, only 23% with a positive TST result had a positive QFT result and, unlike the TST results, positive QFT results correlated with increased risk of TB exposure. Chun et al³¹ also found that, among 227 BCG-vaccinated children in South Korea, the QFT results were more closely associated with exposure to a TB case than were TST results.

The most convincing evidence of increased specificity of the IGRAs would be a natural history experiment following up untreated children who have positive TST results and negative IGRA results, but these observations are scarce. Ling et al³² evaluated how clinicians in Montreal are using IGRA results to determine management of children. Among 55 children with positive TST results and negative QFT

results who were TB contacts, the negative QFT result changed management in only 3 children; 52 children received isoniazid. In 201 children with positive TST results and negative QFT results who were tested in school and immigration screenings, 145 did not receive treatment, and none developed TB disease in 1 year of follow-up. However, given the ages of the children in this study, few cases of TB disease would have been expected even if all these children were infected with *M tuberculosis*. Even given the limitations of available data, the sum of all published studies supports the concept that the IGRAs are more specific than the TST in children. Despite the greater apparent specificity of IGRAs, the decision of whether to treat a patient who has positive TST results and negative QFT results should be based on clinical judgment that takes into consideration the age of the patient, risk stratification, and the degree of exposure.

Test Sensitivity in Children

The analysis of studies in children regarding the sensitivity of the IGRAs compared with TST is far more difficult, and the results have been highly variable. The best information comes from the meta-analyses of studies of children with TB disease, diagnosed either by using culture results or clinical diagnosis.^{25–28} Sun et al²⁷ found a sensitivity for all TB disease in children of 70% for ELISA (range: 57%–96%), 62% for ELISPOT (range: 40%–100%), and 71% for the TST (range: 43%–100%). When the analysis was divided into cases of culture-confirmed TB and clinically diagnosed TB, the sensitivities were 85% and 64% for ELISA (mostly QFT), 76% and 58% for ELISPOT (mostly T-SPOT), and 85% and 66% for the TST, respectively. All 3 tests had lower sensitivity in clinically diagnosed cases; there are many possible explanations, including misdiagnosis of TB in the

clinically diagnosed group. Although this meta-analysis found no significant difference in test performance between settings of high and low TB burden, 2 other meta-analyses found the sensitivity of IGRAs to be lower in settings with high TB burden, although the number of studies was small.^{25,26} Two more recent studies conducted in settings with high TB burden also found low sensitivity of IGRAs for TB disease, and they did not add value to the clinical data and conventional tests for diagnosis of TB disease in these children.^{33,34}

The sum of all published studies suggests that the IGRAs are not more sensitive than TST (likely less sensitive in settings of high TB burden) or other measures of determining TB disease in children and cannot be used to rule out TB disease. However, there is some evidence that the sensitivity is increased when both a TST and IGRA are performed, and the use of both tests will increase the rate of positive results in high-risk settings. Hill et al³⁵ investigated child household contacts of adult TB cases in The Gambia. Overall agreement between the TST and ELISPOT was 83%, with each test being positive in 32% of the children, and neither test was affected by BCG vaccination. An additional Gambian study demonstrated a 10% sensitivity benefit for using both a TST and IGRA in children at high risk.³⁶

Indeterminate/Invalid Results in Children

Indeterminate (preferably called invalid in relation to the T-SPOT test) results occur most commonly when the test sample is negative but the positive control has insufficient activity; however, they also occur when the background activity in the negative control is too high. Indeterminate/invalid results may occur because of technical factors, most frequently inadequate shaking of the QFT tubes after the patient's sample has been added. Rates of indeterminate/

invalid results among children have varied between 0% and 35%, but most studies have reported rates in the range of 0% to 10%.^{26,37–42} The rates have been slightly lower with the more recent versions of the commercially available tests. Indeterminate/invalid rates generally are higher among subjects with compromised immune systems whose T lymphocytes cannot mount an adequate response to the positive control, especially people with HIV infection⁴³; they have also been noted to be higher in children with poorly controlled inflammatory bowel disease, hepatitis, malaria, and helminthic infection.^{44,45} Many, but not all, studies have found that otherwise healthy children younger than 5 years are more likely to have indeterminate/invalid test results than older children and adolescents.^{40,46–49}

Test Performance in Immunocompromised Children

Data are scarce for determining the sensitivity and specificity of the IGRAs for immunocompromised children who are at increased risk of developing TB disease if they are infected with *M tuberculosis*. Three systematic reviews of the performance of IGRAs in HIV-infected subjects, mostly adults, concluded that the T-SPOT test may be slightly more sensitive than the QFT (72% vs 61%), but neither was more sensitive than the TST.^{43,50,51} Several small studies have included children with HIV infection and produced varied results; in general, the IGRAs perform poorly and have less concordance with the TST in children with advanced HIV infection, especially if they have concomitant malnutrition.^{52,53} Two small studies have examined the performance of the IGRAs and the TST in children with cancer. Stefan et al⁵⁴ found that among 37 children with untreated cancer in Cape Town, South Africa (a region with extremely high

rates of TB), 7 had positive results with at least 1 test; there was a higher rate of positive results with the T-SPOT, poor concordance among the TST and IGRAs, and a high rate of test failure because of low cell counts. During a contact investigation of 18 children in a pediatric hematology-oncology ward after a patient was found to have pulmonary TB, only 2 patients had a positive T-SPOT result, and this test had more invalid/indeterminate results than the QFT.⁵⁵

Screening for TB risk factors should be performed before any immunosuppressing therapy is given, but it is especially important before therapy with immunomodulating biologic agents, such as monoclonal antibodies against tumor necrosis factor α .³ This topic has been the subject of many small studies in adults that were reviewed in 2 papers.^{56,57} Unfortunately, there are no published studies involving children. For these patients, test sensitivity is more important than specificity because of the increased risk of progression of LTBI to TB disease. In most of the published studies, adult patients had already been treated with a variety of immunosuppressing agents, which may have affected the results of the TST or IGRAs. Rates of indeterminate/invalid results were higher than usual in these patients because of immunosuppression by both disease and drugs. The current evidence does not consistently suggest that IGRAs are better than the TST in identifying subjects who will benefit from treatment of LTBI. It is commonly recommended that all patients, regardless of specific TB risk factors, who will be receiving an immunomodulating biologic agent should be tested for LTBI before starting the therapy. Many experts have suggested that both the TST and an IGRA should be performed for patients who also have a risk factor for LTBI, and appropriate treatment of LTBI should be started if either test result

is positive once TB disease has been ruled out.^{56–60}

Effect of Age on Test Results

There has been a hesitancy to use IGRAs in children younger than 5 years because of a lack of data for this age group and concerns about inadequate sensitivity of the IGRAs. Because infants and young children are more likely than older children to have progression from untreated LTBI to TB disease and young children are more prone to develop serious forms of TB, failure to accurately diagnose TB infection in this age group can have dire consequences.⁷ Resolution of this issue has been hampered by the lack of a reference standard for LTBI. The earliest studies suggested that IGRA sensitivity is diminished in young children, but the results were inconsistent.^{26,41} However, several more recent studies have demonstrated better performance of the commercially available IGRAs in young children. Debord et al⁶¹ found that among 19 children with TB disease, 6 of 10 children younger than 2 years and 9 of 9 children 2 to 5 years of age had a positive QFT result. Moyo et al⁶² studied 397 children in South Africa who were younger than 3 years and were suspected of having TB disease. Agreement between the QFT and TST was 94%, but both tests had lower sensitivity for TB disease (38% for QFT and 35% for the TST) than has been reported in older age groups. Although the IGRAs have low sensitivity for detecting TB disease in young children whose immune responses may be blunted by malnutrition and TB itself, it is not clear whether they have a higher sensitivity for detecting TB infection in otherwise healthy children. Pavić et al⁶³ studied 142 healthy BCG-vaccinated children in Croatia who had recently been exposed to infectious TB disease. Both

the QFT and the TST had rates of positive results that were associated with degree of exposure, and there was no evidence that age affected QFT performance. Critselis et al⁴⁹ performed a TST and QFT in 761 healthy Greek children in 4 age groups who were referred for several indications. Among the 198 children younger than 5 years (74 were younger than 2 years), infants with positive QFT results produced a greater mean titer of INF- γ than older children and adolescents. Agreement between the TST and QFT results was not significantly different between younger and older children. However, the rate of indeterminate results was significantly greater in younger (8.1%) than in older (2.7%) children. It is clear that the use of the TST in infants and young children who received a BCG vaccine will lead to some false-positive results caused by cross-reaction with the BCG. Although some experts support the use of IGRAs to test for LTBI in infants and young children, especially those at low risk of TB infection who have received a BCG vaccine, others do not recommend their routine use in children younger than 5 years until more supportive data are available.

In summary, if an IGRA is performed in an infant or young child, a positive result likely indicates infection with *M tuberculosis*, but a negative result does not rule it out. The rates of indeterminate/invalid results seem to be higher in infants and toddlers than in older children.

Strategies for the Use of IGRAs in Children

Some of the major differences between the TST and the IGRAs are summarized in Table 1. The basis for deciding which diagnostic test to use is fundamentally different for a child than for an adult, and it differs between the diagnosis of LTBI and TB disease. When testing otherwise healthy subjects, the purpose of the TST or an IGRA is to determine

whether the person is infected with *M tuberculosis* and will benefit from treatment. In truth, the positive predictive value of both tests for the development of TB disease is poor in adults and children 5 years or older because, at most, 5% to 10% of those who test positive and go untreated will develop TB disease in their lifetime. In this regard, there is little difference between the TST and the IGRAs. However, children younger than 2 years with untreated TB infection have a 30% to 40% risk of developing TB disease within 1 year; therefore, optimizing test sensitivity is important for this age group. In addition, because children tend to tolerate the treatment of LTBI much better than adults, their risk of adverse events caused by treatment is less. However, test specificity is also an issue, especially for children who have received a BCG vaccine or who have a likelihood of exposure to NTM in their environment; testing them by using the TST will lead to an appreciable proportion of false-positive results when the prevalence of TB infection is low, as in the United States.

Both the TST and the IGRAs are imperfect methods. As a result, **only children who have a risk factor for**

TB infection, have a disease or condition that may require significant therapeutic immunosuppression, or are suspected of having TB disease should be tested with either method. However, a negative result from either type of test is not reliable for excluding the presence of TB disease. Deciding which test to use involves a consideration of sensitivity and specificity. When high specificity is desired (eg, otherwise low-risk BCG-vaccinated children), the IGRAs are the superior tests. Neither method has a clear advantage in sensitivity; when sensitivity is the main concern, a positive result with either the TST or IGRA should be considered indicative of infection with *M tuberculosis*. When sensitivity is paramount, such as high suspicion of TB disease or testing a child who has a TB risk factor and who will soon receive an immunomodulating biologic agent, both an IGRA and a TST should be performed. Performing both tests will lower the overall specificity and lead to some false-positive results, but in children with a high risk of progression to TB disease, this outcome is often an acceptable trade-off.

TABLE 1 Comparison of the TST and IGRAs

Characteristic	TST	IGRA
Antigens used	Many; PPD	3 (QFT) or 2 (T-SPOT)
Sample	Intradermal injection	Blood draw
Patient visits required	2	1
Distinguish between LTBI and TB disease	No	No
Cross-reactivity with BCG	Yes	No
Cross-reactivity with NTM	Yes	Only rare species ^a
Differing positive values by risk	Yes (5-10-15)	No
Causes boosting	Yes	No
Subject to boosting by previous TST	Yes	Possible
Durability over time (stays positive with or without treatment)	Yes	Unknown
Difficulties with test reproducibility	Yes	Yes
Relative cost	Lower	Higher
Location of need for trained staff	"Bedside"	Laboratory
Estimated specificity in BCG-unvaccinated children	95% to 100%	90% to 95%
Estimated specificity in BCG-vaccinated children	49% to 65%	89% to 100%
Estimated sensitivity (confirmed TB disease)	75% to 85%	80% to 85%
Estimated sensitivity (clinical TB disease)	50% to 70%	60% to 80%

^a *M marinum*, *M kansasii*, *M szulgai*, and *M flavescens*.

Figure 1 and Table 2 show potential strategies for testing. Some specific points are:

- Only children who have a risk factor for TB infection, are about to undergo significant immunosuppression, or are suspected of having TB disease should be tested with a TST or an IGRA.
- There is no compelling evidence to support the use of one IGRA over the other.
- If the child has been exposed recently to an infectious case of TB disease, he or she should be evaluated and treated accordingly if either a TST or IGRA result is interpreted to be positive.
- Even with a negative initial test result, contacts of a person with known TB

should be retested in 8 to 10 weeks regardless of whether the initial test used was a TST or IGRA.

- For children 5 years or older, either the TST or an IGRA can be used.
- For children 5 years or older who have received a BCG vaccine, 2 strategies can be used:
 - (1) an IGRA can be used and the result acted on; or
 - (2) a TST can be performed, and if the result is negative, no further testing is necessary; if the result is positive, an IGRA can be performed, and its result acted on.
- When testing for LTBI, some experts will use an IGRA in children 2 to 4 years of age, especially if they have received a BCG vaccine. Most experts

do not currently use an IGRA when testing for LTBI for children younger than 2 years because of lack of data for this age group and the high risk of progression to disease.

- When evaluating a child of any age for TB disease, both a TST and one or both IGRAs can be performed to maximize sensitivity. However, neither method can be used to rule out TB disease.
- For children diagnosed with an immunosuppressing disease or who are about to start immunosuppressive therapy of any kind, testing should be performed with either a TST or IGRA, even in the absence of a recognized TB risk factor. If the child does have a TB risk factor,

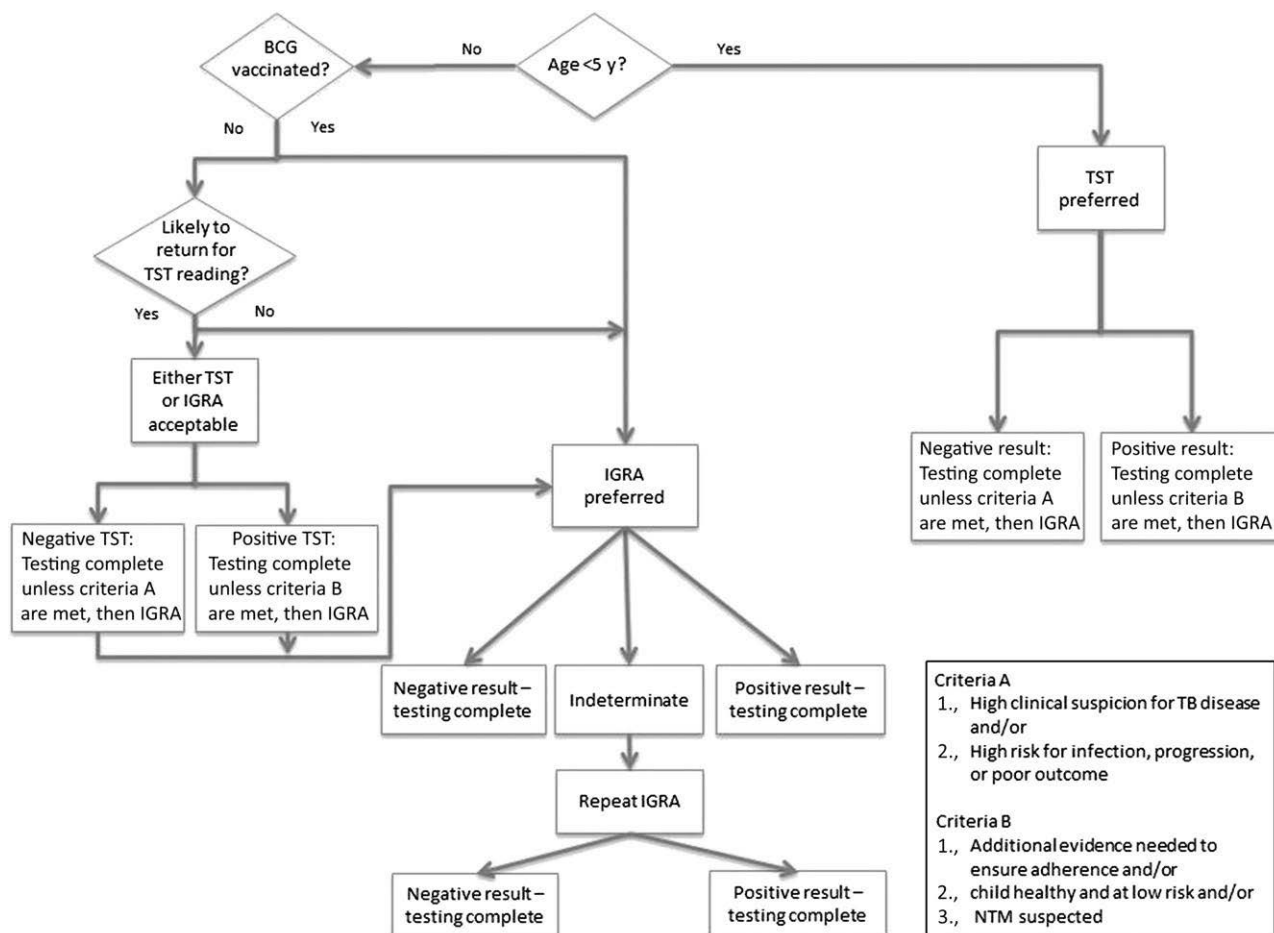


FIGURE 1

An algorithm for the use of the TST and IGRAs in children. Entry into the algorithm assumes that the child has at least 1 risk factor for TB infection.

TABLE 2 Suggested Uses of TST and IGRA in Children

TST preferred

- Children younger than 5 y^a

IGRA preferred, TST acceptable

- Children 5 y or older who have received BCG vaccine
- Children 5 y or older who are unlikely to return for the TST reading

Both the TST and an IGRA should be considered when:

- The initial and repeat IGRA results are indeterminate/invalid
- The initial test (TST or IGRA) result is *negative* and:
 - There is clinical suspicion of TB disease^b
 - The child has a TB risk factor and is at high risk of progression and poor outcome (especially therapy with an immunomodulating biologic agent, such as a TNF- α antagonist)^b
- The initial TST is *positive* and:
 - The patient is 5 years or older and has a history of BCG vaccination
 - Additional evidence is needed to increase adherence with therapy

TNF- α , tumor necrosis factor α

^a Some experts will use an IGRA in children 2 to 4 years of age, especially if they have received a BCG vaccine but have no other significant risk factors. Most experts do not use an IGRA for children younger than 2 years because of lack of data for this age group and the high risk of progression to disease.

^b A positive result of either test is considered significant in these groups.

testing should be performed with both the TST and an IGRA.

- When an IGRA result is indeterminate/invalid, either a repeat IGRA test using the same or the other IGRA can be performed, ensuring proper technique of specimen collection and processing, or a TST can be performed.

CONCLUSIONS

The IGRAs are an advance in the diagnosis of TB infection and disease in children. They have greater specificity than the TST and can greatly reduce the number of false-positive results and unnecessary treatment in children who have received a BCG vaccine or who have been exposed to NTM. The sensitivity of the IGRAs seems to be no better than the TST, but combining them with a TST may increase sensitivity for the diagnosis of TB disease or the detection of TB infection in children at particularly high risk of having progression from TB infection to TB disease. For children 5 years or older, IGRAs can be

used in any situation in which a TST would be used. Because of the relative lack of data concerning the reliability of negative IGRA results in young children and the need for sensitivity in these children because of their increased risk of progression to disease, the IGRAs should not be used to detect LTBI in children younger than 2 years. The IGRAs have the advantages of requiring only a single health visit and have more objective measurement in the laboratory. Although these tests are more expensive than the TST, their use may be more economical than the TST because of the elimination of many false-positive results.⁶⁴

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Iodine Deficiency, Pollutant Chemicals, and the Thyroid: New Information on an Old Problem

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- *Policy Statement*

POLICY STATEMENT

Iodine Deficiency, Pollutant Chemicals, and the Thyroid: New Information on an Old Problem

COUNCIL ON ENVIRONMENTAL HEALTH

KEY WORDS

lactation, goiter, perchlorate, iodine, iodide, thiocyanate, water pollution, nitrate, supplements

ABBREVIATIONS

AAP—American Academy of Pediatrics

EPA—Environmental Protection Agency

FDA—Food and Drug Administration

NIS—sodium iodide symporter

TSH—thyroid-stimulating hormone

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abstract

FREE

Many women of reproductive age in the United States are marginally iodine deficient, perhaps because the salt in processed foods is not iodized. Iodine deficiency, per se, can interfere with normal brain development in their offspring; in addition, it increases vulnerability to the effects of certain environmental pollutants, such as nitrate, thiocyanate, and perchlorate. Although pregnant and lactating women should take a supplement containing adequate iodide, only about 15% do so. Such supplements, however, may not contain enough iodide and may not be labeled accurately. The American Thyroid Association recommends that pregnant and lactating women take a supplement with adequate iodide. The American Academy of Pediatrics recommends that pregnant and lactating women also avoid exposure to excess nitrate, which would usually occur from contaminated well water, and thiocyanate, which is in cigarette smoke. Perchlorate is currently a candidate for regulation as a water pollutant. The Environmental Protection Agency should proceed with appropriate regulation, and the Food and Drug Administration should address the mislabeling of the iodine content of prenatal/lactation supplements. *Pediatrics* 2014;133:1163–1166

ADEQUACY OF IODINE INTAKE IN THE UNITED STATES

Adequate iodine intake, usually as iodide, is necessary to produce thyroid hormone. Adequate thyroid hormone production is critical in pregnant women and neonates because thyroid hormone is required for brain development in children.¹ Severe, untreated hypothyroidism in infancy results in irreversible cretinism, but milder iodine deficiency can also affect cognitive development of the child. The “goiter belt” of endemic iodine deficiency in the United States had largely been eliminated by iodizing table salt in 1924; however, iodine deficiency increased from the 1970s through the 1990s, and approximately one-third of pregnant women in the United States are marginally iodine deficient.^{2,3} Processed foods in the United States are prepared with noniodized salt,⁴ and consumption of these processed foods has increased. Although studies of cognitive development in infants whose mothers were marginally iodine deficient revealed inconsistent results,^{5,6} any morbidity resulting from iodine deficiency can and should be prevented. Although there are a few instances in which governments have required the use of

iodized salt in processed foods,⁷ this option has not been well studied and is not likely to occur in the United States soon. The Salt Institute, the trade group for salt manufacturers, has a goal of universal salt iodization, but it claims that companies are reluctant to switch to iodized salt for fear that taste or other characteristics of the processed food would be altered.

The American Thyroid Association⁸ and the National Academy of Sciences⁹ recommend that lactating women have an intake of 290 μg of iodide per day, which generally requires a supplement with 150 μg of iodide. In the United States, although most pregnant and lactating women take supplements, only 15% to 20% take supplements that contain any iodide.¹⁰ Many prenatal/lactation vitamins do not contain iodide, and those containing iodide are often formulated to have 150 μg or less of potassium iodide, which should yield approximately 120 μg or less of iodide, which is below the recommended amount of 150 μg . In addition, there is wide variability in the measured iodide content of supplements.¹¹

POLLUTANT CHEMICALS AND IODINE DEFICIENCY

Commonly encountered environmental chemicals might augment the effects of iodine deficiency by competing for transport by the sodium-iodide symporter (NIS). The NIS is an integral plasma membrane glycoprotein found in the thyroid gland and the lactating mammary gland, among other tissues.¹² The NIS mediates the active transport of iodide into the thyroid follicular cells, making it available to iodinate dehydroxylated tyrosine for the first step in thyroid hormone synthesis. In the mammary gland, the NIS mediates transport of iodide into milk, making it available

to the infant. Although the NIS has a high affinity for iodide, other anions, such as thiocyanate, nitrate, and perchlorate, can compete with (and be transported as) iodide and thus decrease iodide concentration within the thyroid gland or milk. Although such transport might be expected to lead to increased concentrations of nitrate, thiocyanate, and perchlorate in human milk, only perchlorate exposure and excretion have been found to be significantly higher in breastfed infants under normal circumstances.^{13,14}

Thiocyanate and nitrate are well-known and commonly encountered chemicals. Exposure to thiocyanate comes from cruciferous vegetables and tobacco smoke (including secondhand smoke), and exposure to nitrate comes from drinking water and some leafy and root vegetables. Perchlorate (ClO_4^-) may be less familiar. It is an inorganic anion used industrially as an oxidizer for rocket fuels and propellants and in explosives. It also occurs naturally, usually in arid regions, such as in the southwestern United States. Perchlorate is 10 to 100 times more potent than iodide or the other anions in competing for the NIS. It has become a widespread environmental contaminant. The Environmental Protection Agency (EPA) detected perchlorate in approximately 4% of US public drinking water systems.¹⁵ Perchlorate has also been detected in cow milk as well as in a variety of other foods. In a nationwide survey, the US Food and Drug Administration (FDA) detected perchlorate in at least 1 sample of 74% of foods analyzed.¹⁶ Analysis of samples gathered in the NHANES (2001–2002) revealed widespread human exposure to perchlorate; all 2820 spot urine specimens analyzed contained perchlorate, and the median urine perchlorate concentration in the US population was 3.6 $\mu\text{g/g}$ of creatinine.¹⁷ Perchlorate

competitively inhibits iodide uptake, and high-dose exposure will decrease thyroid function.^{18,19} There is some evidence that perchlorate interferes with thyroid hormone economy at background exposures in the United States. In the NHANES (2001–2002), female participants 12 years and older with lower iodide status and higher urinary perchlorate had higher serum thyroid-stimulating hormone (TSH) and lower serum thyroxine concentrations.¹⁷ In a smaller study in infants, both boys and girls with lower urinary iodide and higher perchlorate concentrations had higher urinary TSH and, unexpectedly, higher thyroxine concentrations.²⁰ That study also reported increases in TSH concentration associated with thiocyanate and nitrate concentrations in urine of infants.

The EPA, in February 2011, made a regulatory determination for perchlorate in accordance with the Safe Drinking Water Act.²¹ This is the first of several steps in the direction of limiting the amount of perchlorate in drinking water, which should ultimately decrease exposure to mothers and infants. This action initiates a process to develop and establish a National Primary Drinking Water Regulation. Once the National Primary Drinking Water Regulation is finalized, certain public water supplies will be required to take action to comply with the regulation in accordance with the schedule specified in the regulation.

Iodine deficiency is undesirable *per se* because of its potential harm to the developing nervous system. Iodine deficiency may also make the mother and child more vulnerable to environmental agents that compete with iodine for transport into thyroid tissue. The effective regulation of perchlorate by the EPA should decrease exposure but it will not do so

quickly. With regard to thiocyanate and nitrate, young infants should not be exposed to tobacco smoke or drinking water with excess nitrate; few consume enough cruciferous, leafy, or root vegetables for these sources to be of concern. For breastfeeding mothers, perchlorate exposure may be currently unavoidable, but breastfeeding should not be discouraged because of the presence of perchlorate or other environmental chemicals. Nitrate and thiocyanate in the maternal diet do not appear to increase a breastfed child's exposure. In summary, many US women of reproductive age are marginally iodine deficient. Iodine deficiency per se can interfere with normal brain development in their offspring; in addition, it increases vulnerability to the effects of certain environmental pollutants. Women should take a prenatal/lactation supplement with adequate iodide. Such supplements are not currently labeled accurately, but the FDA is moving to correct this situation.

RECOMMENDATIONS FOR CLINICIANS

Pediatricians should be aware that pregnant women and breastfeeding mothers, and thus their infants, may be iodine deficient. Breastfeeding mothers should take a supplement that includes at least 150 μg of iodide and use iodized table salt (combined iodide intake should be between 290 and 1100 μg of iodide per day). If the mother is vegan or does not consume dairy or fish, testing urine to check for iodine deficiency may be indicated. If an opportunity arises to advise a woman who is pregnant or planning to become pregnant about supplementation, the pediatrician should provide similar guidance.

Breastfeeding mothers should avoid excess nitrate both to avoid potential

interference with iodide transport and to prevent methemoglobinemia in their infants.²² Water is the usual source of excess nitrate. Municipal water supplies are regulated, but nitrate is a common pollutant of private wells. The American Academy of Pediatrics (AAP) recommends that well water be checked annually.²³

Interested pediatricians should contact the AAP Department of Federal Affairs about ways they can support regulation by the FDA and EPA. Both agencies need to recognize the hazard to children posed by the current situation.

Tobacco smoke is a source of thiocyanate exposure. The AAP has a detailed policy about the prevention of tobacco smoke exposure.²⁴ Pregnant women should be advised not to smoke and to avoid all exposures to secondhand tobacco smoke.

RECOMMENDATIONS FOR GOVERNMENT

The current reported state of discordance between the label and the actual content of iodide in supplements is unacceptable. As Leung et al¹¹ stated, "Manufacturers of prenatal multivitamins in the United States should be encouraged to use only potassium iodide, to maintain consistency in labeling, and to ensure that these vitamins contain 150 μg of supplemental daily iodide by including at least 197 μg of potassium iodide per daily dose, as recommended by the American Thyroid Association." The FDA is aware of this situation and was investigating it as of fall 2013. The FDA should attempt to correct this situation and, if voluntary action on the part of the suppliers is insufficient, do what is necessary to allow consumers to identify and use iodide supplements with confidence.

The EPA has begun the regulatory process to establish a national primary drinking water regulation for perchlorate. Because of the potential effect on children, the AAP encourages the EPA to complete the regulatory process in as expeditious a manner as possible.

State and local governments should enact clean-air and smoke-free environment ordinances and legislation in their communities and states, particularly for environments in which children learn, live, and play, such as schools, multiunit housing, public parks, child care settings, public beaches, sidewalks, restaurants, and sporting arenas. These environments should be smoke free, even when children are not present.²⁴

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Literacy Promotion: An Essential Component of Primary Care Pediatric Practice

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- *Clinical Report*

POLICY STATEMENT

Literacy Promotion: An Essential Component of Primary Care Pediatric Practice

abstract

FREE

Reading regularly with young children stimulates optimal patterns of brain development and strengthens parent-child relationships at a critical time in child development, which, in turn, builds language, literacy, and social-emotional skills that last a lifetime. Pediatric providers have a unique opportunity to encourage parents to engage in this important and enjoyable activity with their children beginning in infancy. Research has revealed that parents listen and children learn as a result of literacy promotion by pediatricians, which provides a practical and evidence-based opportunity to support early brain development in primary care practice. The American Academy of Pediatrics (AAP) recommends that pediatric providers promote early literacy development for children beginning in infancy and continuing at least until the age of kindergarten entry by (1) advising all parents that reading aloud with young children can enhance parent-child relationships and prepare young minds to learn language and early literacy skills; (2) counseling all parents about developmentally appropriate shared-reading activities that are enjoyable for children and their parents and offer language-rich exposure to books, pictures, and the written word; (3) providing developmentally appropriate books given at health supervision visits for all high-risk, low-income young children; (4) using a robust spectrum of options to support and promote these efforts; and (5) partnering with other child advocates to influence national messaging and policies that support and promote these key early shared-reading experiences. The AAP supports federal and state funding for children's books to be provided at pediatric health supervision visits to children at high risk living at or near the poverty threshold and the integration of literacy promotion, an essential component of pediatric primary care, into pediatric resident education. This policy statement is supported by the AAP technical report "School Readiness" and supports the AAP policy statement "Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health." *Pediatrics* 2014;134:404–409

STATEMENT OF NEED

Reading aloud with young children is one of the most effective ways to expose them to enriched language and to encourage specific early literacy skills needed to promote school readiness. Indeed, early, regular parent-child reading may be an epigenetic factor associated with later reading success.^{1,2} Yet, every year, more than 1 in 3 American children

COUNCIL ON EARLY CHILDHOOD

KEY WORDS

literacy promotion, reading aloud, early brain development, language development, child development, school readiness

ABBREVIATIONS

AAP—American Academy of Pediatrics

ROR—Reach Out and Read

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start kindergarten without the language skills they need to learn to read. Reading proficiency by the third grade is the most important predictor of high school graduation and career success. Approximately two-thirds of children each year in the United States and 80% of those living below the poverty threshold fail to develop reading proficiency by the end of the third grade. Children from low-income families hear fewer words in early childhood and know fewer words by 3 years of age than do children from more advantaged families. Children from low-income families have fewer literacy resources within the home, are less likely to be read to regularly, and are more likely to experience early childhood adversity and toxic stress at an early age, all resulting in a significant learning disadvantage, even before they have access to early preschool interventions.^{3–6}

The 2011–2012 National Survey of Children's Health found that 60% of American children from birth to 5 years of age from families whose incomes were 400% of the federal poverty threshold or greater were read to daily, and only 34% of children from families whose incomes were below 100% of the poverty threshold were read to daily.⁷ These numbers indicate that, even in higher-income families, many children do not experience the enhanced engagement and language-rich parent-child interactions, including book handling, print exposure, and other early literacy experiences, afforded by daily shared reading. All families face issues of limited time, limited parental understanding of the key role of reading aloud, and competition for the child's interest and attention from other sources of entertainment, such as electronic media.⁸ In contrast to often either passive or solitary electronic media exposure, parents reading with young children is a very personal and nurturing experience that promotes parent-child interaction,

social-emotional development, and language and literacy skills during this critical period of early brain and child development.

LANGUAGE AND LITERACY DISPARITIES

Reading with children in their infancy and preschool years is associated with higher language skills at school entry and with childhood literacy acquisition.^{9–11} After controlling for family education and socioeconomic status, the literacy-related qualities of a child's home are associated with language skill development.^{12,13} Earlier age of initiation of reading aloud with a child has been shown to be associated with better preschool language skills and increased interest in reading.¹⁴ Reading aloud with young children has been found to increase the richness of the vocabulary to which they are exposed as well as the complexity of syntax.¹⁵ In addition, books and early conversations and play around books and reading stimulate increased interaction between the adult and child.¹⁶ These interactions build nurturing relationships that are critical for the child's cognitive, language, and social-emotional development.¹⁷

Hart and Risley⁵ identified dramatic differences in early language exposure of 1- and 2-year-olds in low-income families compared with children in higher-income families. Cognitive and linguistic differences in children from talkative versus taciturn families were impressive by 3 years of age and persisted into school age. Indeed, 60% of the variance in vocabulary in these children at 8 and 9 years of age could be explained by their exposure to language at home, before they were 3 years old. Book sharing has been shown to promote social interaction between caregiver and child and to encourage literacy development.^{16,17} Children's literacy skills at school entry and in kindergarten and first grade often predict their later reading success.^{18–20}

Children from low socioeconomic backgrounds are significantly more likely to have reading problems, to repeat a grade, and to have learning disabilities diagnosed.^{21,22} Poor reading skills in adults are associated with poor economic potential and with the perpetuation of cycles of poverty, poor health, and dependency across the life course.²³

DATA LINKING HEALTH TO LITERACY

Health literacy is “the degree to which individuals can obtain, process, and understand basic health information and services needed to make appropriate health decisions.”²⁴ The 2003 National Adult Assessment of Literacy estimated that 14% of US adults had below basic literacy and 22% more had only basic literacy, which results in more than 90 million adults in the United States who may lack the literacy needed to effectively negotiate the health care system.²⁵ Research has revealed compelling associations of diminished disease knowledge, decreased utilization of preventive services, increased hospitalization, poorer overall health status, poorer control of chronic illness, and higher mortality in adults with limited health literacy.^{26–30} This interplay of health and development means that low literacy and related low health literacy in parents of young children pose a range of additional risks, with studies showing increased developmental risk for children associated with reduced reading aloud and increased health risk related to medication dosing errors and lower rates of adherence to medical regimens.^{31,32}

DATA SUPPORTING OFFICE-BASED PRACTICE OF LITERACY PROMOTION AS AN EFFECTIVE INTERVENTION

There are many literacy programs that promote reading to children. Reach Out and Read (ROR) is the most widely studied and disseminated model of

literacy promotion in the child's medical home. Multiple studies in high-risk populations show that the ROR model, which includes advising parents of infants, toddlers, and preschool-aged children about the importance of reading aloud, counseling parents about specific book-related strategies, modeling, and providing developmentally appropriate books to children at health supervision visits, results in parents being more likely to read with their children regularly.^{1,35–35} In addition, these children are more likely to have significantly improved language development by the age of 24 months compared with their peers who did not participate in these programs.¹ Parents participating in ROR reported a more positive attitude toward books and reading. For example, when asked to name favorite activities with their child or their child's favorite activities, parents were significantly more likely to mention looking at books and reading aloud than were parents in control groups who had not received the ROR intervention. This significant increase in parents viewing reading with young children as a favorite activity has been found in English- and Spanish-speaking parents, including recent immigrant populations.^{1,35,36} One study evaluated families who spoke languages in which no books were available. These families were given English books and still showed increased positive attitudes and practices.³⁷

Well-designed studies using appropriately matched comparison families or randomized controlled trials of ROR have revealed differences in children's expressive and receptive language.^{1,2,36,38} In one study, there was a 6-month developmental increase in receptive language skills of children (average age, 4 years) whose families were participating in ROR, and children with more contacts with ROR had larger increases in their language skills.² In another

study, larger vocabulary size was evident in intervention children by the time they were 18 to 25 months old.¹ ROR has also been found to contribute positively to a child's home literacy environment.³⁹ A multicenter study of 19 primary care sites in 10 states before and after introducing ROR showed increased parental support for reading aloud after the program was implemented.⁴⁰ In addition, a program modeled after ROR for implementation in collaboration with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was shown to be associated with improved school readiness.⁴¹ A recent randomized controlled trial of enhanced intervention building on ROR showed that additional intervention during the first 6 months of life leads to increased reading activities in infancy, reduced infant electronic media exposure, and increased parent-child interactions in children from low-income, immigrant, inner-city families. This reduced media exposure was a direct result of the increase in reading activities.^{42,43}

Research, in summary, shows that in populations at risk, participation in the ROR intervention is associated with markedly more positive attitudes toward reading aloud, more frequent reading aloud by parents, improved parent-child interactions, improvements in the home literacy environment, and significant increases in expressive and receptive language in early childhood.⁴⁴

PROGRESS INTEGRATING LITERACY PROMOTION INTO PRIMARY CARE AND THE NEED FOR ADVOCACY

The ROR model has been voluntarily adopted by more than 5000 pediatric primary care sites serving children at risk and has thus been field tested widely and found to integrate effectively into primary care in a variety of settings. The model includes training in the techniques for using books to enrich

and expedite primary care visits. This training is already incorporated into the majority of pediatric residency programs, so newly trained pediatricians are likely to have learned pediatric literacy promotion as part of how to deliver quality primary care, again reflecting the evidence base supporting the efficacy of the intervention. Initiatives partnering with the AAP are currently underway to increase literacy promotion and the adoption of the ROR model to serve several important groups, including American Indian, Native Hawaiian, and Alaska Native populations.⁴⁵ Another initiative, partnering with the AAP Section on Uniformed Services, is developing ways to foster literacy promotion in medical facilities serving military families. Local and national partnerships with public libraries, adult and family literacy programs, child care providers, schools, and businesses can help pediatricians connect families to more books, more skills, and more opportunities to facilitate the safe, stable, and nurturing relationships associated with long-term academic success and health.

Support and advocacy from the AAP will make it more likely that financial support can be found for pediatricians who want to follow this model. Many pediatricians believe that their patients could benefit from this intervention, but ongoing book supply is often a barrier, as are the time pressures already crowding the primary care visit. Costs in both books and time can be offset in great measure by the many ways that a book can enrich the interactions among children, parents, and pediatric providers at visits. The simple practice of incorporating a book into the health supervision visit allows for direct observation of emergent language and literacy skills and parent-child interactions around shared reading, as well as an opportunity to provide concrete guidance around language, development, and daily routines. In addition, books and

the guidance that accompanies them improve families' satisfaction with the care and advice they receive and strengthen their bond with their primary care provider and medical home.⁴⁶

RECOMMENDATIONS FOR PEDIATRICIANS

The AAP recommends that pediatric providers promote early literacy development as an important evidence-based intervention at health supervision visits for children beginning in infancy and continuing at least until the age of school entry by engaging in the following:

1. Advising all parents that reading aloud with their young children can enrich parent-child interactions and relationships, which enhances their children's social-emotional development while building brain circuits to prepare children to learn language and early literacy skills.
2. Counseling all parents about developmentally appropriate reading activities that are enjoyable for the child and the parents and offer language-rich exposure to books and pictures and the written word.
3. Providing developmentally, culturally, and linguistically appropriate books at health supervision visits for all high-risk, low-income children and identifying mechanisms to obtain these books so that this does not become a financial burden for pediatric practices.
4. Using a robust spectrum of options to support and promote these efforts, including wall posters and parent information materials that are culturally competent and accessible to those with limited literacy skills themselves, as well as information about the locations of and services offered by their local public libraries and mechanisms for accessing books for distribution. The AAP provides a literacy toolkit

(available at www2.aap.org/literacy/index.cfm) for pediatric and educational professionals and for parents to support this work.

5. Partnering with other child advocates to influence national messaging and policies that support and promote these key early shared-reading experiences.

In addition, as described in the AAP technical report "School Readiness," pediatric providers can also promote the "5 Rs" of early education:

1. Reading together as a daily fun family activity;
2. Rhyming, playing, talking, singing, and cuddling together throughout the day;
3. Routines and regular times for meals, play, and sleeping, which help children know what they can expect and what is expected from them;
4. Rewards for everyday successes, particularly for effort toward worthwhile goals such as helping, realizing that praise from those closest to a child is a very potent reward; and
5. Relationships that are reciprocal, nurturing, purposeful, and enduring, which are the foundation of a healthy early brain and child development.³

RECOMMENDATIONS FOR POLICY MAKERS

1. The AAP supports incorporation of literacy promotion and training related to language and literacy development into pediatric resident education. The integration of literacy promotion as a key component of primary care should be taught in resident continuity experiences and evaluated as an element of competency-based pediatric medical education.
2. The AAP supports federal and state funding for children's books to be provided at pediatric health supervision visits for children at high risk as

well as the incorporation of funding for children's books in managed care and government insurance programs for children at high risk.

3. The AAP supports research on the effects of pediatric early literacy promotion on child health and educational outcomes and research on best practices for literacy promotion in the context of both pediatric practice and of residency education.

SUMMARY

Providing books at pediatric primary care visits to families at economic and social risk, together with developmentally appropriate anticipatory guidance encouraging parents to read aloud with their children, has a powerful effect on the home environment of young children. It directly affects language development, a major factor in school readiness, during the critical period of early brain development. The costs of these books, of training primary care providers, and of incorporating these strategies into the primary care visit constitute an investment in infants, toddlers, and preschool children directed at their language, literacy, social-emotional, and life course development. As Professor James Heckman argued in his keynote address at the 2007 AAP National Conference and Exhibition, programs that invest in children at the earliest ages have the highest rates of return. By initiating early support for reading aloud, modifying the home environment to be richer in print, and advising parents about enjoyable and playful book-related strategies that will increase their children's language and early literacy skills within the context of their critically important nurturing relationships with their parents and caregivers, pediatric providers can leverage their unique opportunity to influence children in the very early years of life and to create important long-term relationships with families.

All families need to hear the important message that reading aloud to their children is crucial, especially in an era in which competing entertainment imperatives, such as screen time (television, cinema, video games, and computers), may limit family interactions and live language exposures of even very young children.^{47,48} Although most research has focused on literacy promotion for families of lower socioeconomic status, pediatricians should remember to educate all families about the importance of reading aloud to young children because even in affluent and educated families with plenty of books at home, many parents do not read with their children on a daily basis. Promoting literacy with parents of children beginning in infancy supports the recommendations of the AAP that children younger than 2 years not view electronic media and that older children and youth have no more than 2

hours daily of media exposure by offering parents a positive alternative for entertaining young children, for nurturing early relationships, and for developing healthy bedtime routines. The positive reinforcement of repeated developmentally appropriate encouragement in the context of the primary care visit reminds parents again and again of the importance of their “face time,” interactive conversations, and their own evolving and essential relationship with their children, which is critical to setting a young child’s developmental trajectory and life course.

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Maintaining and Improving the Oral Health of Young Children

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- *Policy Statement*

POLICY STATEMENT

Maintaining and Improving the Oral Health of Young Children

abstract

FREE

Oral health is an integral part of the overall health of children. Dental caries is a common and chronic disease process with significant short- and long-term consequences. The prevalence of dental caries for the youngest of children has not decreased over the past decade, despite improvements for older children. As health care professionals responsible for the overall health of children, pediatricians frequently confront morbidity associated with dental caries. Because the youngest children visit the pediatrician more often than they visit the dentist, it is important that pediatricians be knowledgeable about the disease process of dental caries, prevention of the disease, and interventions available to the pediatrician and the family to maintain and restore health. *Pediatrics* 2014;134:1224–1229

INTRODUCTION

Dental caries is the most common chronic disease of childhood. Twenty-four percent of US children 2 to 4 years of age, 53% of children 6 to 8 years of age, and 56% of 15-year-olds have caries experience (ie, untreated dental caries, filled teeth, teeth missing as a result of dental caries).¹ For children 5 to 19 years of age, children from poor and racial or ethnic minority families have higher rates of untreated dental caries than do their peers from nonpoor and nonminority families.² For some age groups, the incidence of dental caries has decreased or stayed the same, but for the youngest children, it has increased.³ Among 6- to 8-year-olds and 15-year-olds, caries experience and untreated dental decay remained mostly unchanged between 1988–1994 and 1999–2004.¹ In children 2 to 4 years of age, the caries experience increased significantly, from 19% to 24%, during that same time period. The increase in the caries experience and untreated caries was statistically significant in children from poor families.

THE ETIOLOGY AND PATHOGENESIS OF DENTAL CARIES

A dynamic process takes place at the surface of the tooth that involves constant demineralization and remineralization of the tooth enamel (the caries balance).^{4,5} Multiple factors affect that dynamic process and can be manipulated in ways that tip the balance toward disease (demineralization) or health (remineralization). These factors include bacteria, sugar, saliva, and fluoride. Because these factors can be

SECTION ON ORAL HEALTH

KEY WORDS

dental, fluoride, oral health, pediatrician, teeth

ABBREVIATION

AAP—American Academy of Pediatrics

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manipulated, it is possible for pediatricians and families to prevent, halt, or even reverse the disease process. Different oral structures and tissues have different and distinct microbial communities (microbiomes).⁶ The oral microbiome at the surface of the tooth is referred to as dental plaque. During the disease process of dental caries, bacteria that are aciduric and acidogenic predominate in the dental plaque. *Streptococcus mutans* is most strongly associated with dental caries, although other bacterial species have these capabilities and thus can also be pathogenic. When environmental factors make it possible to select for these pathogenic bacteria in dental plaque, the disease process begins.

A key environmental factor that allows for selection and proliferation of these pathogenic bacteria is dietary sugar intake. Because these pathogenic bacteria have the ability to ferment sugars, produce acid, and decrease the pH of the dental plaque, they make possible the selection of other aciduric, acidogenic bacteria that will contribute to disease. As more bacteria produce more acid, the pH at the surface of the tooth decreases. This process causes the demineralization of the tooth enamel. Unimpeded, these long periods of low pH and demineralization will result in cavitation.

Saliva is an important factor in buffering the low pH and bringing these demineralization pressures back to a balance with remineralization. In addition to acting as a buffering agent, saliva also flushes the oral cavity of food particles and provides an environment rich in calcium and phosphate to aid in remineralization. When salivary flow is impeded, the pH is able to decrease to a lower level, tipping the scales toward demineralization (disease); in addition, the time it takes to buffer back to a normal pH is longer.⁷

Another important factor that can affect the balance of demineralization

and remineralization is fluoride. More in-depth reviews of fluoride are available elsewhere.^{8–10} It is important, however, for pediatricians and other child health care providers to understand how fluoride influences the caries balance. Fluoride has 3 key effects on the caries balance: (1) inhibition of demineralization at the tooth surface; (2) enhancement of remineralization, which results in a more acid-resistant tooth surface; and (3) inhibition of bacterial enzymes.¹¹ The primary effect of fluoride is topical, via fluoridated toothpastes, mouth rinses, and varnishes, although there is still value in systemic fluoride exposures via fluoridated water and supplements.^{9,11}

PREVENTIVE STRATEGIES

Caries Risk Assessment

Ideally, primary prevention efforts will anticipate and prevent caries before the first sign of disease. Preventive strategies for this multifactorial, chronic disease require a comprehensive and multifocal approach that begins with caries risk assessment. Assessing each child's risk of caries and tailoring preventive strategies to specific risk factors are necessary for maintaining and improving oral health. There is no single test that takes into consideration all risk factors and accurately predicts an individual's susceptibility to caries. However, pediatricians can conduct an excellent risk assessment for caries by focusing on the key risk factors for dental caries that are associated with diet, bacteria, saliva, and status of the teeth (both current status and previous caries experience). The American Academy of Pediatrics (AAP)/Bright Futures Oral Health Risk Assessment Tool can be found at <http://www2.aap.org/oralhealth/RiskAssessmentTool.html>.¹²

Sugars (but not sugar substitutes) are a critical risk factor in the development of caries. The risk of caries is greatest if sugars are consumed at high frequency and are in a form that

remains in the mouth for long periods of time.¹³ Thus, key behaviors that place a child at high risk of caries include continual bottle/sippy cup use (especially with fluids other than water), sleeping with a bottle (especially with fluids other than water), frequent between-meal snacks of sugars/cooked starch/sugared beverages, and frequent intake of sugared medications.

Early acquisition of *S mutans* is a major risk factor for early childhood caries and future caries experience.¹⁴ Strong evidence demonstrates that mothers are a primary source of *S mutans* colonization for their children.¹⁵ Thus, an important factor associated with caries risk in young children is the recent or current presence of active dental decay in the primary caregiver. Prevention, diagnosis, and treatment of oral diseases are highly beneficial, can be undertaken, and should be encouraged during pregnancy with no additional fetal or maternal risk compared with the risk of not providing care.¹⁶ The most important and predictive risk factor for caries, however, is previous caries experience. This finding is not surprising, considering that the factors which initiated the disease process often continue to exist over time.

Other caries risk factors are associated with salivary flow and the status of the teeth. Diseases (eg, diabetes mellitus, Sjögren's syndrome, cystic fibrosis) and medications (eg, antihistamines, anticonvulsants, antidepressants) that result in xerostomia (decreased salivary flow) reduce the availability of saliva to buffer the acid produced by pathogenic bacteria, thus enhancing their ability to cause damage to the teeth. In addition, the teeth of preterm infants, which frequently have enamel defects, are at increased susceptibility for disease. Older children who have deep pits and fissures in their molars are also at increased susceptibility for disease.

Anticipatory Guidance

With a clear understanding of the etiology of dental caries and the risk factors that lead to and facilitate the spread of this disease, pediatricians can target anticipatory guidance to assist families in preventing it. Because the disease of dental caries is multifocal, the anticipatory guidance should also be multifocal. Pediatricians should concentrate their anticipatory guidance on topics that can affect the risk of disease.

Dietary Counseling

Because sugar intake is such an important risk factor for dental caries, pediatricians can incorporate anticipatory guidance associated with preventing dental caries into discussions with families about dietary habits and nutritional intake. Pediatricians should counsel parents and caregivers on the importance of reducing the frequency of exposure to sugars in foods and drinks. To decrease the risk of dental caries and ensure the best possible health and developmental outcomes, pediatricians should recommend that parents do the following:

- Exclusively breastfeed infants for 6 months and continue breastfeeding as complementary foods are introduced for 1 year or longer, as mutually desired by mother and infant.¹⁷
- Discourage putting a child to bed with a bottle. Establish a bedtime routine conducive to optimal oral health (eg, brush, book, and bed).
- Wean from a bottle by 1 year of age.
- Limit sugary foods and drinks to mealtimes.
- Avoid carbonated, sugared beverages and juice drinks that are not 100% juice.
- Limit the intake of 100% fruit juice to no more than 4 to 6 oz per day.
- Encourage children to drink only water between meals, preferably fluoridated tap water.

- Foster eating patterns that are consistent with guidelines from the US Department of Agriculture.

Oral Hygiene

The value of good oral hygiene lies in controlling the levels and activity of disease-causing bacteria in the oral cavity and delivering fluoride to the surface of the tooth. It is important to remember that pathogenic bacteria can be passed from caregiver to child.¹⁸ Thus, anticipatory guidance for both parent and child is important. Key anticipatory guidance points regarding oral hygiene are as follows:

- Parents/caregivers should be encouraged to model and maintain good oral hygiene and a relationship with their own dental provider.
- Parents/caregivers, especially those with significant history of dental decay, should be cautioned to avoid sharing with their child items that have been in their own mouths.
- The child's teeth should be brushed twice a day as soon as the teeth erupt with a smear or a grain-of-rice-sized amount of fluoridated toothpaste. After the third birthday, a pea-sized amount should be used.
- Parents/caregivers should help/supervise a child brushing his or her teeth until mastery is obtained, usually at around 8 years of age.

Fluoride

The delivery of fluoride to the teeth includes community-based options (water fluoridation), self-administered modalities (fluoride toothpaste and supplements), and professional applications (fluoride varnish). Each of these delivery mechanisms is useful in preventing dental caries.

Water fluoridation is a community-based intervention that optimizes the level of fluoride in drinking water, resulting in preeruptive and posteruptive protection of the teeth.¹⁹ Water fluoridation is a

cost-effective means of preventing dental caries, with the lifetime cost per person equaling less than the cost of 1 dental restoration.^{20,21} Most bottled waters do not contain an adequate amount of fluoride.

Fluoride toothpaste is an important way to deliver fluoride to the surface of the tooth. Fluoride toothpaste has been shown to be effective in reducing dental caries in both primary and permanent teeth.^{22,23} It is important to limit the amount of toothpaste used to a smear or a grain-of-rice-sized amount for young children and no more than a pea-sized amount for children older than 3 years.²⁴ Fluoride supplements should be prescribed for children whose primary source of drinking water is deficient in fluoride.²⁵

Fluoride varnish is a professionally applied, sticky resin of highly concentrated fluoride. Two or more applications of fluoride varnish per year are effective in preventing caries in children at high risk of all ages.⁸ In most states, pediatricians can apply and be paid for application of fluoride varnish to the teeth of young children. Application of fluoride varnish is even more effective when coupled with counseling.²⁶ The US Preventive Services Task Force recently published a new recommendation that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (B recommendation).²⁵ More details and recommendations on fluoride can be found in the AAP clinical report "Fluoride Use in Caries Prevention in the Primary Care Setting."¹⁰

Other Important Anticipatory Guidance Topics

A frequent topic of discussion with parents is nonnutritive oral habits, such as use of pacifiers and thumb sucking. AAP policy states that parents consider offering a pacifier at naptime

and bedtime because of a protective effect of pacifiers on the incidence of sudden infant death syndrome after the first month of life.²⁷ Both finger- and pacifier-sucking habits will only cause problems with dental structures if they go on for a long period of time. Evaluation by a dentist is indicated for non-nutritive sucking habits that continue beyond 3 years of age.²⁸

Dental injuries are common. Twenty-five percent of all schoolchildren experience some form of dental trauma.²⁹ Pediatricians can help prevent such trauma by encouraging parents to cover sharp corners of household furnishings at the level of walking toddlers, recommend use of car safety seats, and be aware of electrical cord risk for mouth injury. Pediatricians can also encourage mouthguard use during sports activities in which there is a significant risk of orofacial injury.³⁰ More information on dental trauma is available in the AAP clinical report "Management of Dental Trauma in a Primary Care Setting."³¹

COLLABORATION WITH DENTAL PROVIDERS

The AAP, the American Academy of Pediatric Dentistry, the American Dental Association, and the American Association of Public Health Dentistry all recommend a dental visit for children by 1 year of age. Although pediatricians have the opportunity to provide early assessment of risk for dental caries and anticipatory guidance to prevent disease, it is also important that children establish a dental home. A dental home is the ongoing relationship between the dentist and the patient, inclusive of all aspects of oral health care delivered in a comprehensive, continuously accessible, coordinated, and family-centered way.³²

Unfortunately, little is known about pediatric health care providers' dental referral behaviors and patterns. Al-

though 1 study found that children 2 to 5 years of age who received a recommendation from their health care provider to visit the dentist were more likely to have a dental visit,³³ the US Preventive Services Task Force found no study that evaluated the effects of referral by a primary care clinician to a dentist on caries incidence.³⁴ It is also noteworthy that preschool-aged children covered by Medicaid who had an early preventive dental visit by 1 year of age were more likely to use subsequent preventive services and to have lower dental expenses.³⁵

With early referral to a dental provider, there is an opportunity to maintain good oral health, prevent disease, and treat disease early. Establishing such collaborative relationships between physicians and dentists at the community level is essential for increasing access to dental care for all children and improving their oral and overall health.

CONCLUSIONS

Oral health is an integral part of the overall health and well-being of children.³⁶ A pediatrician who is familiar with the science of dental caries, capable of assessing caries risk, comfortable with applying various strategies of prevention and intervention, and connected to dental resources can contribute considerably to the health of his or her patients. This policy statement, in conjunction with the oral health recommendations of the third edition of the AAP's *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, serves as a resource for pediatricians and other pediatric primary care providers to be knowledgeable about addressing dental caries.³⁷ Because dental caries is such a common and consequential disease process in the pediatric population, it is essential that pediatricians include oral health in their daily practice of pediatrics.

SUGGESTIONS FOR PEDIATRICIANS

1. Administer an oral health risk assessment periodically to all children.
2. Include anticipatory guidance for oral health as an integral part of comprehensive patient counseling.
3. Counsel parents/caregivers and patients to reduce the frequency of exposure to sugars in foods and drinks.
4. Encourage parents/caregivers to brush a child's teeth as soon as teeth erupt with a smear or a grain-of-rice-sized amount of fluoride toothpaste and a pea-sized amount at 3 years of age.
5. Advise parents/caregivers to monitor brushing until 8 years of age.
6. Refer to the AAP clinical report, "Fluoride Use in Caries Prevention in the Primary Care Setting," for fluoride administration and supplementation decisions.
7. Build and maintain collaborative relationships with local dentists.
8. Recommend that every child has a dental home by 1 year of age.

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Management of Dental Trauma in a Primary Care Setting

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- *Clinical Report*

CLINICAL REPORT

Management of Dental Trauma in a Primary Care Setting

abstract

FREE

The American Academy of Pediatrics and its Section on Oral Health have developed this clinical report for pediatricians and primary care physicians regarding the diagnosis, evaluation, and management of dental trauma in children aged 1 to 21 years. This report was developed through a comprehensive search and analysis of the medical and dental literature and expert consensus. Guidelines published and updated by the International Association of Dental Traumatology (www.dental-traumaguide.com) are an excellent resource for both dental and non-dental health care providers. *Pediatrics* 2014;133:e466–e476

INTRODUCTION

By 14 years of age, 30% of children have experienced a dental injury.¹ Many of these children are taken directly to their medical home, an urgent care center, or an emergency department for evaluation and treatment. Few of these facilities employ a dentist; therefore, the primary care provider for the injured child will most likely be a pediatrician or other physician. In many instances, the injured tooth's survival is time-dependent. Therefore, it is imperative for the pediatrician to manage the acute dental injury properly to afford the child's dentition the best possible outcome. Pediatricians can also advocate for dental injury–preventive measures, as they provide other injury-prevention messages for caregivers of children and preparticipation sports physicals.

DENTAL TRAUMA PREVENTION

Pediatricians can advocate for dental injury–preventive measures as they provide other injury-prevention messages during well-child visits. Caregivers should be counseled about participation in sports and activities that are appropriate for the child's age and development, general household safety measures such as stairway gates and removal of trip hazards, and adult supervision of activities that could lead to dental trauma. Although these measures will not prevent all dental injuries, they can reduce their incidence and severity.

As part of a preparticipation sports physical, physicians should recommend sports mouth guards to prevent sports-related mouth injuries. Currently, the US National Collegiate Athletic Association requires mouth guards for 4 sports (ice hockey, lacrosse, field hockey,

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KEY WORDS

dental trauma, dental injury, tooth, teeth, dentist, pediatrician

ABBREVIATION

CT—computed tomography

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and football).² The American Dental Association recommends the use of mouth guards in 29 sports/exercise activities. Sports mouth guards can be made of a variety of materials: polyvinyl acetate-polyethylene or ethylene vinyl acetate copolymer, polyvinyl-chloride, latex rubber, or polyurethane. Mouth guards can be custom made in the dental office from an impression of the patient's maxillary arch and can also be purchased, typically in a store that carries sports-related items. Purchased mouth guards can be customized by boiling the mouth guard to soften the material and then biting into the mouth guard to create an impression of the upper teeth, which helps create a better fit. Stock mouth guards can also be purchased, but they are not as well adapted to the teeth. Impact studies have shown that wearing any type of mouth guard reduces the risk of tooth injury compared with not wearing a mouth guard.

DENTAL TRAUMA ASSESSMENT

For all dental injuries, it is important to follow a systematic approach.³ Before initiating treatment, an abbreviated medical and dental history should be obtained to gain information vital to urgent care. Questions with respect to how, when, and where the dental injury occurred are important for determining the need for a tetanus booster, the possibility of child abuse, and the possibility of a head injury.⁴ Physicians have the legal obligation to explore and report reasonable suspicions of child abuse. Given the proximity of the dentition to the cranium, it is important to complete an age-appropriate neurologic assessment, which may include inquiring whether the child experienced loss of consciousness, dizziness, headache, or nausea and vomiting. If a concussion or a more severe intracranial injury is suspected, then protection of the cervical spine and

immediate medical evaluation should be prioritized.⁵ Specific to the teeth, disturbances in the occlusion (bite) should be assessed because this may reveal a displaced tooth or an alveolar or jaw fracture. Lastly, inquiring about tooth sensitivity or pain to hot and/or cold exposures may indicate that the dentin and/or pulp tissue are exposed, requiring immediate referral to a dentist.

The clinical examination should include thorough evaluation of the face, lips, and oral musculature for soft tissue lesions. To facilitate an accurate extraoral and intraoral examination, the face and oral cavity should be cleansed with water or saline. The facial skeleton should be palpated for signs of fractures. The dental trauma region should be inspected for fractures, abnormal tooth position, and tooth mobility. Identifying whether the injured tooth is a primary versus a permanent tooth is important in the management of certain types of dental injuries. In general, children younger than 5 years are in the primary dentition (Fig 1).^{*} The 20 primary teeth are named alphabetically starting with tooth A in the upper right posterior quadrant. From ages 6 through 12 years, children are in the mixed dentition in which they are exchanging the primary teeth for the permanent teeth. After 8 or 9 years of age, most of the incisors are permanent teeth, with a mixture of primary canines and molars until the age of 12 years. By 13 years of age, most children have exfoliated all of their primary teeth and have 28 permanent

teeth. The permanent teeth follow a numbering system (Fig 2). Discussion with the parent/caregiver as to whether the child has lost any primary teeth from natural exfoliation can help identify whether the child is in full primary dentition or mixed dentition. Primary incisor teeth are considerably smaller in size than permanent teeth. Physicians can use their own dentition as a point of reference to estimate the size of permanent teeth for comparative purposes. In addition to proper tooth identification, the direction of any tooth displacement as well as any pulp involvement should be noted. Familiarity with tooth anatomy will assist in determining the extent of injury present (Fig 3).

After the initial clinical assessment and administration of first aid, the injured region should be examined with the most appropriate radiographic techniques. Radiographic assessment of an injured tooth is best accomplished with conventional intraoral dental radiographs instead of computed tomography (CT). There is considerably less radiation involved with conventional intraoral dental radiographs than with a head CT scan. Several clinical studies have demonstrated that multiple dental radiographs from different angulations are needed to detect displacement of the tooth in its socket as well as presence of root fractures.^{6,7} If a lip laceration is present, an intraoral soft tissue radiograph may be indicated to visualize any foreign bodies, including tooth fragments. These types of radiographs are more feasibly obtained by a dentist because a general emergency department or radiologist's facility may not be equipped to perform radiography, and a dentist's evaluation may be required to order the correct radiographic studies. If a maxillary or mandibular fracture is suspected, a panoramic film, cone-beam CT, or CT scan may be indicated. For all

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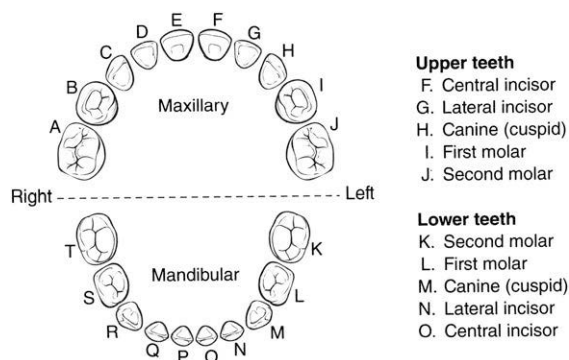


FIGURE 1
Primary dentition.

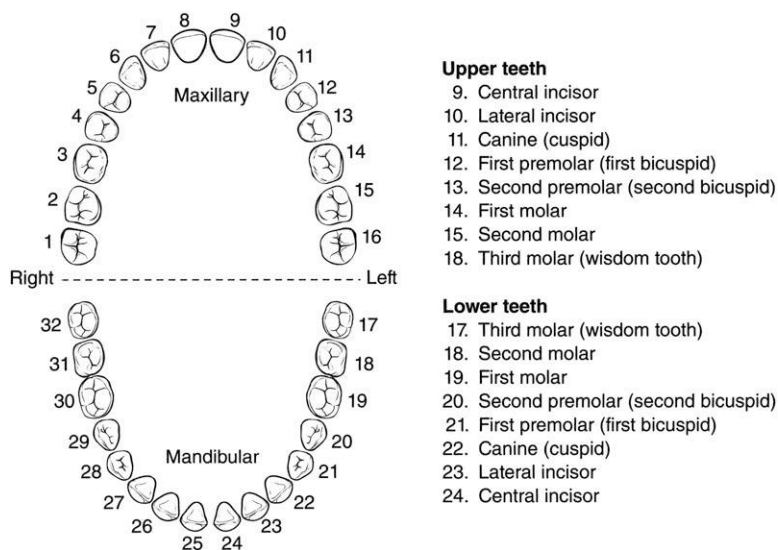


FIGURE 2
Permanent dentition.

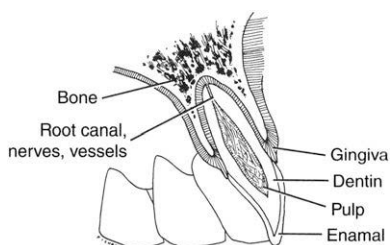


FIGURE 3
Tooth diagram.

radiograph selections with dental trauma, the safety principle of ALARA (as low as reasonably achievable) should be followed to minimize exposure to radiation.⁸

If possible, and with appropriate informed consent, digital photographic documentation of the trauma is helpful because it offers an exact documentation of the extent of injury and can be sent electronically to a consulting dentist for guidance in managing the acute phase of treatment. Photographs can also be used later to facilitate any legal or insurance claims related to the injury.

With the combined information from the clinical and radiographic examinations, a diagnosis can be made, and treatment can be planned. The man-

agement of dental trauma is described here in 2 parts: trauma involving the primary dentition and trauma involving the permanent dentition. Depending on the type of dental injury, there can be distinct differences in how a primary tooth is managed compared with a permanent tooth.

DENTAL TRAUMA CLASSIFICATIONS

Concussion

A concussed tooth is tender to touch, but there is no increased mobility or displacement. There is no sulcular bleeding (at the margin of the tooth and gums).

Subluxation

A subluxated tooth presents with abnormal mobility but no displacement. Sulcular bleeding is present (Fig 4).

Lateral Luxation

Clinically, a luxated tooth is displaced laterally, most often in a palatal/lingual direction (Fig 5). The injured tooth may be mobile or firmly locked into the displaced position.

Extrusive Luxation

Partial vertical displacement of the injured tooth from its socket is classified as an extrusive luxation injury or a partial avulsion (Fig 6).

Intrusive Luxation

In this type of luxation, the tooth is forced into the alveolus and usually locked without any mobility (Fig 7). The tooth appears shortened. In cases of severe intrusion, the tooth may appear to be missing. Bleeding from the gingival sulcus is present.

Avulsion

An avulsion is the complete displacement of the tooth out of the socket (Fig 8). The periodontal ligament is severed, and the alveolus may be fractured.

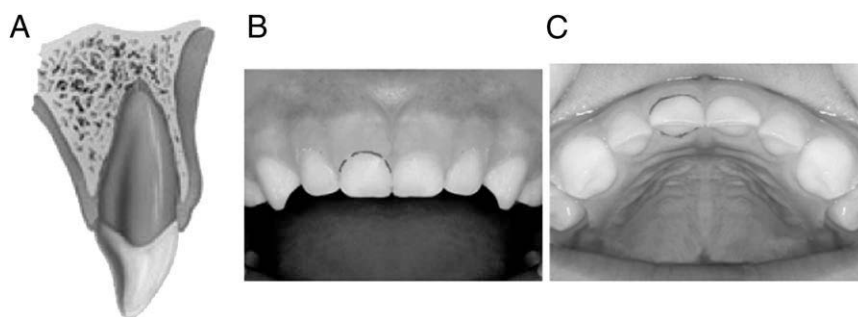


FIGURE 4
Subluxation.



FIGURE 5
Lateral luxation.



FIGURE 6
Extrusive luxation.

Infraction (Crack)

An infraction is a crack or craze line in the surface of the enamel. The tooth appears intact, but crack lines may be visualized by shining a focused source of light, such as the otoscope, onto the crown of the tooth in an axial direction.

Enamel Only (Uncomplicated) Crown Fracture

If the fracture of the tooth is contained within the enamel layer only, it is considered to be an uncomplicated fracture. There is generally limited sensitivity associated with this type of injury unless there is a rough edge

that is causing irritation to the tongue or lips.

Enamel and Dentin (Uncomplicated) Crown Fracture

If the fracture of the tooth is contained within the enamel and dentin layers without exposure of the pulpal tissues, then the injury is classified as an uncomplicated fracture of enamel and dentin. When the dentin is exposed, there is frequently sensitivity associated with exposure to air, food, or beverages (Fig 9).

Crown Fracture With Exposed Pulp (Complicated)

If the fracture of the tooth exposes the pulpal tissue, the injury is classified as a complicated fracture. Crown fractures with exposed pulp are frequently sensitive and introduce an increased risk of infection because the pulp tissue is exposed to the oral flora (Fig 10). In severe fractures, the root may be involved, creating a crown-root fracture (Fig 11).

Root Fracture

When the crown segment of an injured primary incisor displays mobility, there is a risk of a root fracture. This can only be verified with an intraoral dental radiograph (Fig 12).

Alveolar Fracture

Dislocation of several teeth that move together when palpated suggests that there is a fracture of the alveolus (Fig 13).

PRIMARY DENTAL TRAUMA EPIDEMIOLOGY AND MANAGEMENT

Epidemiology

In children 0 to 6 years of age, oral injuries are ranked as the second most common injury, accounting for

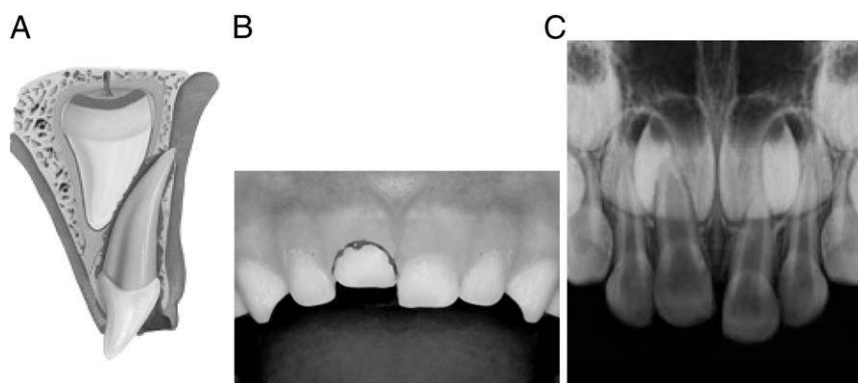


FIGURE 7
Intrusive luxation.



FIGURE 8
Avulsion.

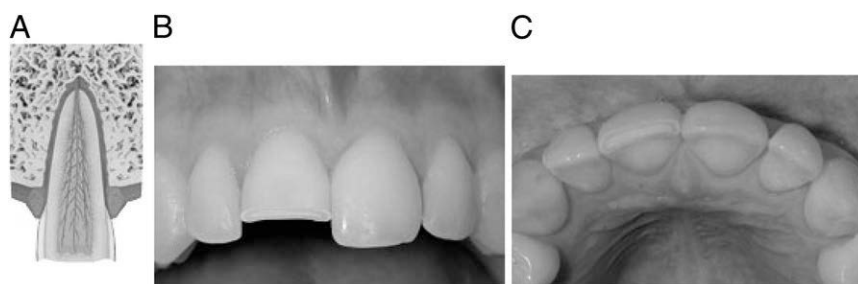


FIGURE 9
Uncomplicated crown fracture (no pulp exposure).

almost 20% of all bodily injuries.⁹ The greatest incidence of trauma to the primary teeth occurs at 2 to 3 years of age, when motor coordination is developing.^{10,11} The most common teeth injured in the primary dentition are the maxillary incisors. These teeth are typically present in the mouth from 12 months to 6 years of

age. Exfoliation of the maxillary incisors may vary from 5 to 7 years of age. The most common dental injury to the primary dentition is a luxation.¹⁰ Dental injuries in the primary dentition occur more often in boys. Child abuse should be considered as a possible etiology in any child younger than 5 years with trauma

affecting the lips, gingiva, tongue, palate, and severe tooth injury.^{12,13}

Concussion

No immediate treatment is indicated for a dental concussion. Observing the injured tooth for possible future pulpal necrosis is recommended. Pulpal necrosis in a primary tooth may cause the tooth to appear gray in color or to have a parulis (gingival abscess or gum boil) on the gingiva adjacent to the root of the affected tooth. If tooth discoloration or a localized parulis forms, then referral to a dentist within a few days is recommended.

Subluxation

No immediate treatment is indicated for a subluxated primary tooth. The injured primary tooth should be followed for possible future pulpal necrosis (as described previously). If tooth discoloration develops or a localized parulis appears, then referral to a dentist within a few days is recommended. If more extensive gingival or facial swelling develops, then immediate referral to a dentist is recommended.

Lateral Luxation

If the tooth displacement is minor, then gentle repositioning is indicated, or acceptance of the position as spontaneous repositioning will take place. For more severe displacement injuries, the child's ability to bite teeth together may be affected. It is important to ensure that the tooth position does not interfere with the occlusion (bite). Asking the child to say "cheese" or the letter "e" allows one to visualize the occlusion and determine whether the luxated tooth is interfering with the complete closure of the bite. If the child is unable to bite the teeth

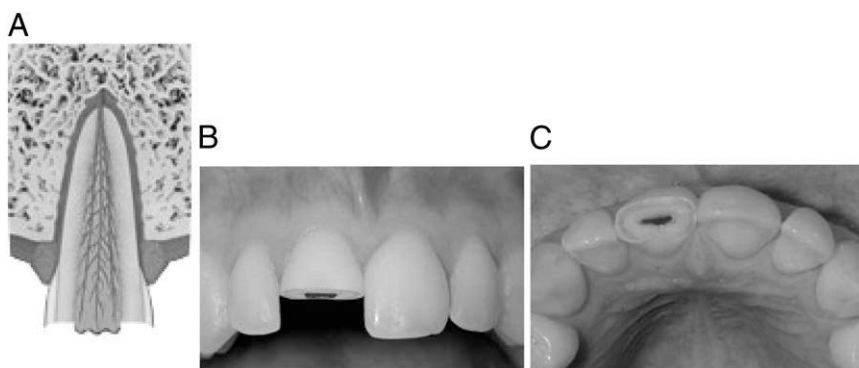


FIGURE 10
Complicated crown fracture (pulp exposure).

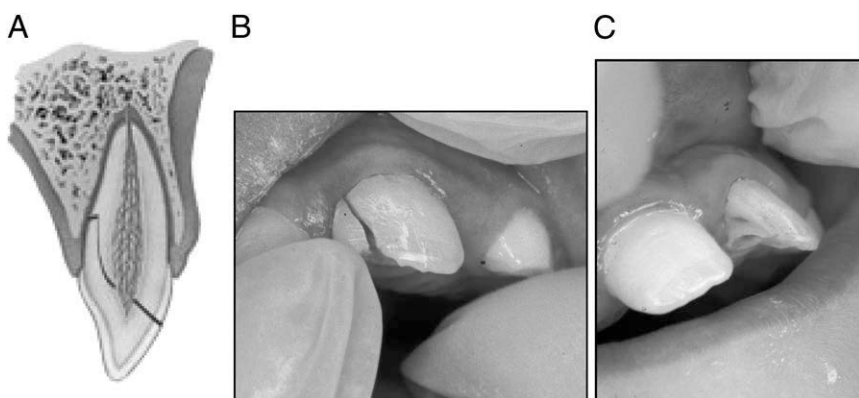


FIGURE 11
Crown root fracture.

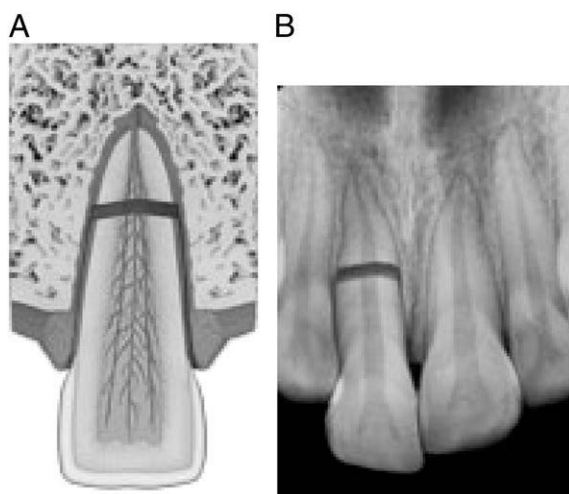


FIGURE 12
Root fracture.

together, then the tooth will need to be repositioned by the urgent care provider, or the child should be im-

mediately referred to a dentist. It is important to ensure that the posterior teeth (molars) are able to fully

interdigitate and masticate food properly. If the luxated tooth is near exfoliation and interfering with the bite, then extraction of the injured tooth is indicated. Immediate referral to a dentist is recommended.

Extrusive Luxation

If the extrusion is minor, then gentle repositioning is indicated. In severe extrusive injuries (>3 mm), extraction is indicated. Immediate referral to a dentist is recommended.

Intrusive Luxation

When a primary tooth is intruded, it will typically reerupt without intervention. In cases of severe intrusion, an intraoral radiograph is indicated to determine the location or absence of the injured tooth. In rare circumstances, the tooth may become ankylosed (fused to bone) and require extraction to prevent blocking of the eruption of the permanent successor. Observation is indicated for all intruded primary incisors. Immediate referral to a dentist is indicated for more severe intrusions or to rule out avulsion of the tooth. With any intruded primary tooth, there is a potential for damage to the developing permanent tooth germ.

Avulsion

When a primary tooth is avulsed and the tooth was found, there is no treatment indicated. An avulsed primary tooth should not be replanted to avoid damage to the underlying permanent tooth germ.⁸ If the tooth is not found, clinical and radiographic examination can confirm that the tooth is not intruded. A chest radiograph may be indicated if the child displays breathing difficulties to ensure the tooth was not aspirated. The subsequent avulsion site will need to be monitored for healing and potential space loss. If the child has an active digit-sucking habit and avulses



FIGURE 13
Alveolar fracture.

a maxillary incisor, the potential for space loss in the upper anterior region exists. An appliance with an artificial tooth may be indicated to prevent space loss.¹⁴ Therefore, referral to a dentist within a few days is recommended to provide space management.

Infraction (Crack)

If the primary tooth sustains a marked crack in the enamel without loss of tooth structure, then placing a resin sealant over the infraction line may be indicated to avoid obvious staining of the line. In many cases, no treatment is indicated; however, the tooth should be monitored for signs of pulpal necrosis until exfoliation.

Enamel Only (Uncomplicated) Crown Fracture

If the fracture of the primary tooth is contained within the enamel surface only, then the tooth fracture area can be smoothed with a dental handpiece and polishing bur or left untreated if the fracture site is smooth to touch. This is best accomplished by a dentist and does not require immediate attention unless there is a sharp edge causing soft tissue injury. The tooth should be monitored by a dentist for signs of pulpal necrosis until exfoliation.

Enamel and Dentin (Uncomplicated) Crown Fracture

A primary tooth with an uncomplicated fracture involving enamel and dentin can be restored with tooth-colored dental material. A referral to a dentist within a few days is indicated; if the child's behavior precludes dental restorative care, then the tooth fracture area can be smoothed with a dental handpiece and polishing bur or left untreated if the fracture site is smooth to touch. The tooth should be monitored by a dentist for signs of pulpal necrosis until exfoliation.

Crown Fracture With Exposed Pulp (Complicated)

If the fracture of the primary tooth exposes the pulpal tissue, then a pulpotomy or pulpectomy and restorative care is indicated. If the child's behavior precludes pulp therapy and dental restorative care, then extraction of the traumatized primary tooth is indicated. If the tooth is treated, then it will need to be monitored for signs of pulpal necrosis until exfoliation. With severe crown fractures, the root may also be involved. If a crown root fracture is suspected, an intraoral periapical radiograph should be obtained to determine the extent of injury to the tooth and root. Extraction of the tooth is indicated if the fracture extends onto the root surface. Immediate referral to

a dentist is indicated for a tooth with a complicated fracture. If the tooth is removed, then a space maintainer may be indicated if the child has an active digit-sucking habit.

Root Fracture

If a root fracture of a primary tooth is suspected because of excessive tooth mobility, then referral to a dentist for a radiographic examination is indicated. The timing of the referral to the dentist is dependent on the amount of crown mobility. If there is concern for aspiration of the crown portion, then immediate referral to a dentist is indicated; subsequent management of the injured tooth is dependent on the location of the root fracture. The closer the root fracture is to the apex of the root, the better the prognosis. This type of root fracture rarely requires treatment. Conversely, the closer the root fracture is to the crown of the tooth, the poorer the prognosis. The crown segment is usually removed, and if the primary root can be removed without damaging the underlying permanent tooth bud, then it can also be extracted. If removal of the root poses a risk to the developing permanent tooth bud, then the residual root can be left and monitored for natural resorption.

Alveolar Fracture

If the trauma involves a fracture of the alveolar bone displayed by dislocation of several teeth that move together, then reposition of the segment and stabilization with a splint is indicated. Immediate referral to a dentist or an oral surgeon is recommended.

Sequelae From Dental Trauma in the Primary Dentition

To optimize the best healing results from trauma sustained by the primary dentition, parents and caregivers should be advised about the

importance of good oral hygiene practices and injury prevention. For the first 10 days after an injury to a primary tooth, the child should eat a soft diet, and sucking on a pacifier or digit should be restricted, if possible.⁹ The routine use of systemic antibiotics in the postoperative care of primary tooth trauma is not indicated.⁹ However, the child's medical condition may require antibiotic coverage. Parents/caregivers should be advised about the potential for crown discoloration, pulp canal obliteration, or pulpal necrosis. Children may not report painful symptoms from a necrotic tooth; therefore, parents/caregivers should be vigilant regarding the development of the symptoms of pulpal necrosis: gingival swelling, increased mobility, and/or parulis. If any of these symptoms develop, the parent/caregiver should obtain follow-up care with the child's dentist to determine the need for extraction of the previously injured tooth.

PERMANENT DENTAL TRAUMA EPIDEMIOLOGY AND MANAGEMENT

Epidemiology

A 12-year review of the scientific literature reports that 25% of all school-age children experience some form of dental trauma.¹⁵ The most common injury reported in the permanent dentition is an uncomplicated crown fracture involving the maxillary incisors. Injuries to permanent teeth are most often caused by falls, followed by automobile crashes, violence, and sports.¹⁶ Sports-related accidents account for 10% to 39% of all dental injuries in children.¹⁷ During sporting activities, falls, collisions, contact with hard surfaces, and contact with sports-related equipment place the child at risk for oral facial injury. Boys sustain more dental injuries to their permanent teeth than girls. During the adolescent years, the possibility of abuse exists and should be

considered in assessing the cause of dental trauma.

Concussion

No treatment is indicated for a concussed permanent tooth. Observing the injured tooth for possible future pulpal necrosis is recommended.

Subluxation

No treatment is indicated for a subluxated permanent tooth. The injured permanent tooth should be followed for possible future pulpal necrosis.

Lateral Luxation

For any amount of displacement, it is important to reposition the tooth to its original position. If the displacement is minor, then gentle digital apical pressure to reposition the tooth is indicated. For more significant displacement, dental forceps may need to be used to reposition the tooth in the proper socket position requiring immediate referral to a dentist. It is important to ensure that the tooth position does not interfere with the occlusion (bite). Asking the child to say "cheese" or the letter "e" allows one to visualize the occlusion and to ensure that the posterior teeth (molars) are able to fully interdigitate and masticate food properly. The permanent tooth will need to be stabilized with a flexible splint for 4 weeks. The tooth should be followed for possible periodontal and pulpal pathology. After severe permanent tooth luxation, it is possible that the tooth will require root canal treatment.

Extrusive Luxation

If the extrusion is minor, gentle digital pressure to reposition the tooth into the socket is indicated. Immediate referral to a dentist for placement of a flexible splint if the tooth remains mobile after repositioning is recommended. If the extrusion is excessive,

then repositioning with dental forceps may be indicated, requiring immediate referral to a dentist. After repositioning, the tooth should be stabilized with a flexible splint for 2 weeks. The dentist will determine the need for pulp therapy depending on the maturity of the root.

Intrusive Luxation

In cases of mild intrusion, the tooth will typically reerupt gradually on its own. Bleeding from the gingival sulcus is present. If no reeruption is visible after a few weeks, orthodontic or surgical repositioning of the intruded tooth is necessary. Early involvement of a dentist is important to supervise the repositioning of the intruded incisor. In severe intrusion cases, the tooth may not be visible clinically, requiring intraoral radiography to be performed to assess the position of the tooth within the alveolus. In rare circumstances, the intruded tooth may become ankylosed (fused to bone) and require extraction to prevent warping of the alveolar ridge, followed by placement of an artificial tooth.

Avulsion

Avulsion of a permanent tooth is the most serious of all dental injuries.¹⁸ The prognosis of the permanent tooth depends on measures taken immediately after the accident. The treatment of choice is immediate replantation. After the tooth is located, it should be handled by the crown portion only and not the root because the root is covered in fragile fibroblasts important for reattachment to the alveolus. Before replantation, it should be confirmed that the avulsed tooth is a permanent tooth; primary teeth should not be replanted. If the permanent tooth is dirty, it should be washed briefly (10 seconds) under cold running water and repositioned

in the socket. The patient/parent should be encouraged to replant the tooth at the site of the injury. The child should be instructed to bite on a cloth to hold it in position until he or she can get to the doctor's office or emergency department. If this is not possible, the tooth should be placed in a suitable storage medium (eg, a glass of cold milk or balanced salt solution, if available). If no storage media are accessible, then the patient can drool saliva into a container and use that as a transport medium. Storing an avulsed tooth in water should be avoided because water causes osmotic lysis of the root fibroblasts. After the tooth has been replanted or placed in a proper storage medium, dental care should be obtained immediately. A flexible splint will need to be placed by the dentist for up to 2 weeks. Most teeth will require root canal therapy, which will need to be instituted within 7 to 10 days after replantation. The tooth should be monitored for the potential of bodily rejection in the form of root resorption. Systemic antibiotics are indicated after reimplantation of an avulsed permanent tooth. For children older than 12 years, doxycycline is the recommended antibiotic, and for children younger than 12 years, penicillin is indicated. For children who are allergic to penicillin, clindamycin is recommended.

Infraction (Crack)

If the permanent tooth sustains a marked crack in the enamel without loss of tooth structure, then placing a resin sealant over the infraction line may be indicated to avoid obvious staining of the line.

Enamel Only (Uncomplicated) Crown Fracture

If the fracture of the permanent tooth is contained within the enamel layer only, then the tooth fracture area can be smoothed with a dental handpiece

and polishing bur or left untreated if the fracture site is smooth to touch. There is generally little or no sensitivity associated with fractures involving enamel, so immediate referral to a dentist is not necessary. The tooth should be monitored for signs of pulpal necrosis.

Enamel and Dentin (Uncomplicated) Crown Fracture

If the fracture of the permanent tooth is contained within the enamel and dentin surfaces without exposure of the pulpal tissues, then the tooth can be restored with tooth-colored dental material, or if the tooth fragment is available, it can be rebonded to the tooth. When dentin is exposed, there may be tooth sensitivity, and the patient should be referred to a dentist within a few days. The more sensitive the tooth is, the more expediently the patient should be seen by a dentist to cover the exposed dentin and reduce the discomfort. By covering the exposed dentin, the risk of pulpal bacterial contamination is reduced. The tooth should be monitored for signs of pulpal necrosis.

Crown Fracture With Exposed Pulp (Complicated)

If the fracture of the permanent tooth exposes the pulpal tissue, then appropriate pulp therapy should be rendered by a dentist immediately to preserve pulp vitality (Fig 10).¹⁵ The timeliness of pulp therapy is important in the young permanent tooth. The permanent tooth is considered immature until 3 years after eruption. If the tooth is immature, then it will need to be monitored for signs of continued root development and the lack of pulpal necrosis. If the tooth has a mature root, then root canal therapy is usually the treatment of choice. In severe cases, the fracture line can involve the root—hence, it is known as a crown-root fracture. The crown fragment must be removed, and

the health of the remaining fragment must be determined. In some cases, the remaining fragment can be orthodontically extruded and subsequently restored with a full-coverage crown, or the remaining root can be submerged to maintain the alveolar bone for a future implant. For esthetics and space maintenance, the missing crown can be replaced by an orthodontic retainer with a prosthetic tooth or by creating a temporary bridge using the original crown fragment.

Root Fracture

When the crown segment of an injured permanent incisor displays mobility, referral to a dentist for a radiographic examination is indicated to rule out a root fracture. The subsequent management of the injured tooth is dependent on the location of the root fracture. The closer the root fracture is to the apex of the root, the better the prognosis. This type of root fracture rarely requires treatment. Conversely, the closer the root fracture is to the crown of the tooth, the poorer the prognosis. Splinting is recommended for 4 weeks. If crown segment remains mobile after splinting, then the crown segment is removed, and the residual root can be orthodontically extruded, treated with root canal therapy, and restored.

Alveolar Fracture

If the trauma involves a fracture of the alveolar bone displayed by dislocation of several teeth that move together, then reposition of the segment and stabilization with a splint is indicated. Immediate referral to a dentist or an oral surgeon for repositioning and placement of a stabilization wire is indicated.

Sequelae From Dental Trauma in the Permanent Dentition

To optimize the best healing results from trauma sustained by the permanent dentition, parents and caregivers should

be advised on the importance of good oral hygiene practices and injury prevention. For the first 10 days after an injury to a permanent tooth, the child should eat a soft diet, and digit sucking should be restricted, if possible.^{15,18} The routine use of systemic antibiotics in the postoperative care of dental trauma is not indicated (except in cases of permanent tooth avulsion and reimplantation).⁹ The child's medical history may require antibiotic coverage. Parents/caregivers should be advised about the potential for crown discoloration, root resorption, ankylosis, or pulpal necrosis. Parents/caregivers and the child should be vigilant regarding the development of the symptoms of pulpal and periodontal abnormalities subsequent to the dental injury: crown discoloration, gingival swelling, increased mobility, and/or sinus tract (parulis). If any of these symptoms develop, the parent/caregiver should obtain follow-up care with the child's dentist to determine the need for additional treatment of the previously injured tooth.

CONCLUSIONS

This clinical report provides evidence-based recommendations for the management of dental trauma in children 1 to 21 years of age. When dental trauma cannot be avoided through the use of preventive measures, it emphasizes the importance of proper diagnosis, treatment planning, and follow-up care conducive to a favorable outcome for an injured tooth in a pediatric patient. The report provides decision-making strategies to assist pediatricians and other primary care physicians in diagnosing and managing children who experience dental trauma. Table 1 provides a concise summary of this information. Close collaboration between the medical and dental home are also important

TABLE 1 Dental Treatment Plan for Traumatic Injuries in the Primary and Permanent Dentition

Description	Primary Dentition	Permanent Dentition
Concussion/subluxation	Observe, soft foods for 1 wk, dental radiograph to rule out root fracture	Observe, soft foods for 1 wk, dental radiograph to rule out root fracture
Luxation	Reposition tooth or extract, do not splint	Dental radiograph, reposition tooth, splint for 4 wk
Extrusion	Reposition tooth or extract, do not splint	Dental radiograph, reposition tooth, splint for 2 wk
Intrusion	Dental radiograph, observe and allow to reerupt, extract if alveolar plate is compromised	Dental radiograph, observe and allow to reerupt, surgical or orthodontic repositioning, root canal treatment
Uncomplicated crown fracture	Restore tooth, smooth sharp edges, dental radiograph to rule out root fracture	Restore tooth, smooth sharp edges, radiograph to rule out root fracture
Complicated crown fracture	Dental radiograph, pulp treatment, restore or extract tooth, observe for infection	Dental radiograph, pulp treatment, restore tooth, observe for infection, may require root canal treatment
Root fracture	Dental radiograph, extract if root fracture is in middle or cervical third of root	Dental radiograph, splint, may require root canal treatment; if in cervical third, may need to extract
Avulsion	Do not replant, dental radiograph to rule out intrusion if tooth is not located	Do not handle the root, replant within 30 min or place in recommended transport medium (balanced salt solution, cold milk); dental radiograph, replant and splint as soon as possible; systemic antibiotics, soft diet, chlorhexidine, close follow-up

to facilitate the time-sensitive therapies for dental injuries.

Suggestions for Pediatricians

1. Counsel parents/caregivers about ways to reduce the risk of dental trauma through injury-prevention strategies.
2. Establish collaborative relationships with local general and pediatric dentists to facilitate referral of patients with traumatic dental injuries.
3. Understand the differences between treatment recommendations for primary and permanent tooth traumatic injuries.
4. Recognize when traumatic dental injuries require immediate treatment by a dentist.
5. Recognize when traumatic dental injuries can be initially managed by the pediatrician or primary care

physician with subsequent referral to a dentist.

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Nonoral Feeding for Children and Youth With Developmental or Acquired Disabilities

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- *Clinical Report*

CLINICAL REPORT

Nonoral Feeding for Children and Youth With Developmental or Acquired Disabilities

Richard C. Adams, MD, FAAP, Ellen Roy Elias, MD, FAAP, and
COUNCIL ON CHILDREN WITH DISABILITIES

KEY WORDS

nonoral feeding, gastrostomy, fundoplication, shared decision-making, disabilities

ABBREVIATIONS

CNS—central nervous system
GER—gastroesophageal reflux
HRQOL—health-related quality of life
NG—nasogastric
NJ—nasojejunal
QOL—quality of life

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abstract

FREE

The decision to initiate enteral feedings is multifaceted, involving medical, financial, cultural, and emotional considerations. Children who have developmental or acquired disabilities are at risk for having primary and secondary conditions that affect growth and nutritional well-being. This clinical report provides (1) an overview of clinical issues in children who have developmental or acquired disabilities that may prompt a need to consider nonoral feedings, (2) a systematic way to support the child and family in clinical decisions related to initiating nonoral feeding, (3) information on surgical options that the family may need to consider in that decision-making process, and (4) pediatric guidance for ongoing care after initiation of nonoral feeding intervention, including care of the gastrostomy tube and skin site. Ongoing medical and psychosocial support is needed after initiation of nonoral feedings and is best provided through the collaborative efforts of the family and a team of professionals that may include the pediatrician, dietitian, social worker, and/or therapists. *Pediatrics* 2014;134:e1745–e1762

INTRODUCTION

The decision to initiate enteral feedings is multifaceted, involving medical, financial, cultural, and emotional considerations. In 1793, John Hunter wrote of a patient who had a neurologic impairment affecting swallowing: “It becomes our duty to adopt some artificial mode of conveying food into the stomach, by which the patient may be kept alive while the disease continues.”¹ Today we speak of surgical options, medical options, and evidence-based outcomes; caregivers’ beliefs and roles; patient-appropriate individual intervention; family-centered care; and quality of life (QOL) considerations.

Faced with medical, social, and cultural considerations, the family often relies on the pediatrician for guidance in both the decision-making and the management of nonoral feedings. This article integrates cross-discipline information into a functional guide for the pediatrician. Specifically, this clinical report provides:

- an overview of clinical issues in children who have developmental or acquired disabilities that may prompt a need to consider nonoral feedings;
- a systematic way to support the child and family in clinical decisions related to initiating nonoral feeding;

- information on surgical options that the family may need to consider in that decision-making process; and
- pediatric guidance for ongoing care after initiation of nonoral feeding intervention.

BROAD CONSIDERATIONS IN THE NEED FOR NONORAL FEEDINGS

Children who have developmental disabilities or acquired disabilities are at risk for having primary and secondary conditions that affect growth and nutritional well-being. These conditions can manifest as inadequate intake of micronutrients, calories, and/or fluids. Prevalence rates vary greatly, even within diagnostic cohorts. Nonetheless, evidence from the past 2 decades supports the ability to improve nutritional outcomes among children who have neurologic disabilities (eg, cerebral palsy, Rett syndrome, trisomy 21, myelomeningocele).^{2–4}

Deficiencies in micronutrients may develop in children who have underlying metabolic disorders who are treated with medically prescribed specialized diets, such as low-protein diets in patients who have urea cycle disorders. Some caregivers may also self-prescribe special diets to their children, in attempts to organically improve the underlying developmental disability. There is no substantial evidence supporting the addition of generic micronutrients as long as the child's caloric needs are being met through a balanced diet. Restrictive diets may lead to significant nutritional deficiencies unless appropriately monitored.

Among youth who have suboptimal dietary intake, several deficiencies occur more commonly than others. For example, iron deficiency, a relatively high-risk condition for children who have feeding disorders, can affect well-being even when the iron deficiency has not yet created an actual anemia.⁵ It has been associated with sleep disorders

in children and manifestations of inattention.^{6,7} Zinc is important in neurodevelopment; its deficiency is associated with a variety of symptoms, including loss of appetite and skin problems. For patients who have chronic nutritional stressors and comorbid developmental disabilities—particularly if surgery is being planned—the status of other vitamin and micronutrient stores may need consideration.^{8,9} For children who are fed prepared formulas (oral or nonoral) as the primary source of nutrition, micronutrients are provided in sufficient amounts only if the adequate amount of formula is actually being consumed and tolerated.¹⁰

Many youth who have developmental disabilities have comorbid conditions requiring medications. The potential for reciprocal interaction exists: the influence of medication on nutritional status, and the effect of nutritional status on bioavailability and metabolism of medications. Some medications have adverse effects, such as nausea, diminished appetite, or diarrhea. Anti-epileptic drugs can be associated with secondary deficiencies of nutrients such as vitamin D and carnitine. Table 1 includes medication categories and their relationship to nutritional status. For some families, the ability to accurately administer medications orally can be problematic because of dysphagia, dystonia, other disorders of movement or coordination, or clinically significant reflux or emesis.

Among children who have neurodevelopmental disabilities, barriers to adequate oral intake can be related to underlying neurologic dysfunction. The enteric nervous system, developing primarily from the neural crest cells, is the so-called “brain of the gut.” Although it functions independently of the central nervous system (CNS), it also interacts with the CNS by prevertebral ganglia of the spinal cord and/or via the efferent action of the vagus nerve. Among chil-

dren who have underlying differences in CNS development, associated dysfunction in gut motility or gastroesophageal reflux (GER) can contribute to the challenges of ensuring adequate nutritional intake and absorption. Sometimes these problems are progressive and degenerative; it is not uncommon for children who have disorders of energy metabolism (such as mitochondrial disorders) to experience worsening gut dysmotility over time.

Vomiting or retching is relatively common among children who have developmental disabilities. The underlying cause of these can inform decisions about approaches to nonoral feeding. Vomiting attributable to GER can be addressed through a combination of positioning, food or formula selection, medications, assurance that constipation has been alleviated, and/or surgery. Retching is the first stage of the emetic reflex and is not always related to GER. Poor modulation of gastric vagal afferents can act as a potent activator of the forceful emetic reflex. Recognition of this CNS process as the etiology of emesis is important, because this process may well continue even after a fundoplication procedure and can have a negative effect on the surgery's long-term success.^{11–13} Dysmotility, mentioned previously, can also be a contributor to vomiting or retching.

Oropharyngeal incoordination, resultant poor bolus formation, and/or inadequately controlled bolus propulsion can result in subsequent airway penetration or outright aspiration. If sustained, chronic pulmonary dysfunction and/or reactive airway disease can result. These problems, in isolation or in addition to GER or gut dysmotility, may diminish the child's desire to eat orally.¹⁴

Frank aspiration identified in modified barium swallow studies invites the discussion of moving to a nonoral feeding route. However, these studies are rarely so “black and white.” Penetrations of

TABLE 1 Potential Clinical Problems in Selected Medication Use and Nutritional Status

Category	Medication (Examples)	Comment
Anticonvulsants	Valproate	Potential for carnitine, folate, copper, selenium, and/or zinc deficiency
	Phenytoin	Potential for folic acid, calcium, vitamin B ₁ , vitamin B ₁₂ , vitamin D, and/or vitamin K deficiency
	Phenobarbital	Potential for folic acid, calcium, biotin, vitamin D, and/or vitamin K deficiency
	Carbamazepines	Potential for biotin, folic acid, and/or vitamin D deficiency
	Lamotrigine	Occasional nausea and/or vomiting
	Levetiracetam	Potential for biotin, folic acid, and vitamins B ₆ and/or B ₁₂ deficiency
	Topiramate	Renal tubular acidosis and pancreatitis, renal/bladder stones
Stimulants	Methylphenidate and associated stimulants used in attention-deficit/hyperactivity disorder	Appetite suppression Slow height growth Potential for weight loss
Muscle relaxants	Diazepam and others in this class	Highly protein bound; with malnourishment and loss of serum protein there may be enhancement of drug effect Take into consideration re: pain management, respiratory depression
	Baclofen	Constipation
Corticosteroids	Dexamethasone	Increased appetite or diminished appetite; impact on taste Diminished calcium and phosphorous absorption; increased risk for gastritis
Antibiotics		Potential for diarrhea related to gut flora change; probiotic therapy shown to minimize adverse effects
Antidepressants		Reports indicate that among individuals who have major depressive disorder, there may be deficiencies in folate, vitamin B ₁₂ , iron, zinc
Anticholinergics	Oxybutynin	Constipation, dry mouth

some textures may merely require alteration of oral feeding techniques. Techniques of bolus size selection and pacing of bites, for example, may allow a somewhat tedious but acceptable method for continued oral feedings. Thus, these studies may inform decisions, but should not, in isolation, mandate surgical intervention.

Suboptimal fluid intake leads to chronic-intermittent constipation. This, in turn, can result in diminished appetite. The circular pattern of a feeding disorder, leading to diminished safe fluid intake, resulting in constipation, contributing to further feeding disincentives and

even emesis, is too common among children who have neurodevelopmental disabilities.

SPECIFIC CONSIDERATIONS: CHILDREN WHO HAVE A NEED FOR NONORAL FEEDINGS

Detailed description of the vast array of neurodevelopmental or acquired disabilities and their unique nutritional challenges is beyond the scope of this report. In particular, 2 important complex cohorts of children are not included: (1) very preterm or sick neonates being managed in a neonatal ICU,¹⁵ and (2) children receiving prolonged total

parenteral nutrition.¹⁶ Presented below are examples of common conditions associated with nutritional/feeding challenges among children who have special health care needs. Hopefully, these can guide approaches to care for the broader array of children who have special needs seen in pediatric clinical settings.

Children Who Have Cerebral Palsy

Cerebral palsy refers to a group of static brain insults affecting the development of movement and posture, often with differences in tone (diminished, increased, or mixed). The functional implications of insults occurring in early development can extend beyond motor impairments to impairments of visual-motor skills, communication, cognition, and behavior. Similarly, neuromuscular and enteric nervous system dysfunction can manifest as ongoing or worsening issues. Comorbid conditions, such as seizure disorders, hearing impairments, abnormal muscle tone, or postural instability, can be present.¹⁷ Any of these factors (or multiple combinations) can affect eating and swallowing skills, leading to nutritional compromise.¹⁸

Feeding problems for children who have cerebral palsy may manifest as oral fluid/food spillage while feeding, increased length of meals (often confused as “behavioral”), coughing/gagging with feeding, recurrent lower respiratory infections, GER, and/or nasal reflux from the posterior pharynx. These or other “red flags” suggestive of dysphagia should be considered when the child fails to grow or maintain appropriate health.^{19,20}

For decades, identifying the best method to evaluate and monitor growth and nutrition in children who have cerebral palsy has challenged pediatricians. Weight, weight-for-height, segmental measures, skinfold measures, and other techniques each have some value, but none is easily and consistently applied

with assurance of accuracy across the population of children who have cerebral palsy.^{21,22}

In the pediatric medical home, serial measures of the child's weight remain the most common practice; this offers a useful way to track trends in growth and nutrition longitudinally. Obtaining consistent measures in a clinic setting can be challenging but can be enhanced by use of a consistent scale (balanced to 0 at each visit) and by weighing the child consistently in light clothing, with a dry diaper, and without shoes, orthotic bracing, wheelchairs, or other confounders. Weights should be plotted on standard growth charts at each visit.^{23,24}

Consultation with a pediatric dietitian can be useful when there are declines in trends of weight, struggles with feeding/drinking patterns, GER, constipation, or compromised bone health. A detailed analysis of protein, fluid, calorie, or fiber intake; mealtime patterns; socioeconomic factors; and behavioral factors can facilitate approaches to optimal intake and growth. The overall energy expenditure of the child, including changing manifestations of spasticity or dystonia, deserves consideration when changing trends in weight are noted.²⁵ After the aforementioned factors have been addressed in an effort to support successful oral feeding, if the child remains unable to safely and effectively meet his or her nutritional requirements orally, options for adjunctive nonoral feedings should be considered.

Children Who Have Myelomeningocele

A common feature among children who have myelomeningocele is the presence of a Chiari II malformation, which can be associated with central apnea and/or dysphagia. In infants, the "suck, swallow, breathe" rhythm can be disrupted. Excessive gag reflex can be confused

with GER. Children who have vocal cord dysfunction related to the Chiari II malformation may require tracheotomy; not uncommonly, nonoral feeding via gastrostomy tube is recommended for pulmonary safety.

Development of the enteric nervous system takes place as neural crest-derived cells migrate and differentiate.²⁶ Dysmotility in children who have spina bifida, related to alterations in the enteric nervous system and altered parasympathetic innervations, can manifest from the esophagus downward throughout the intestinal tract. Modified barium swallow studies performed carefully to replicate *actual* feeding circumstances can be greatly helpful in symptomatic children. If alteration of textures and changes in feeding techniques fail to support adequate nutrition and/or safe oral feedings, options including nonoral feedings must be discussed. As children grow into early elementary school age, the anatomy of the head, oropharynx, and neck shift in relative proportions. A repeat modified barium study may be warranted to define new parameters of safe feeding.

Among children who have thoracolumbar-level myelomeningocele who demonstrate severe kyphoscoliosis, peculiar chest/abdomen anatomy, or both, feeding problems can occur related to posture, positioning, underlying internal anatomy, and GER. These, in concert with dysphagia related to the Chiari II malformation, create complex feeding challenges.

Adequate nutrition is critical to maintenance of skin integrity. Too often, the combination of insensate skin, moist skin, and exposure to local tissue injury results in significant wounds among children who have myelomeningocele. Successful management of serious wounds demands higher intake of protein, calories, and micronutrients.²⁷ Children who are marginally able to

meet their fluid and nutritional needs orally may need adjunctive feedings for relatively short duration (8 weeks or less) to promote wound healing; others may require nonoral feeds for longer periods.

Children Who Have Cleft Conditions and/or Micrognathia

Micrognathia (mandibular hypoplasia) has its origin in the first trimester of intrauterine development. The abnormally high position of the tongue can result in a cleft of the soft palate. A severe form of this process results in the Robin sequence. The recessed jaw and tongue are often associated with low tone and weakness of facial musculature, increasing the risks for airway obstruction and aspiration of oral feedings.²⁰ For infants affected by these conditions, nasogastric tube feeding or gastrostomy tube feeding may be required from birth for months at a minimum.²⁸ Reid and colleagues provide an excellent review of feeding issues relative to cleft lip, cleft palate, Pierre-Robin sequence, and other cleft conditions. Their longitudinal studies spotlight the conditions for which adjunctive nonoral feeding measures might be indicated.²⁹

Children Who Have Neurodevelopmental Disabilities

GER is a common finding among children who have neurodevelopmental disabilities.³⁰ The reflux can be related to a spectrum of underlying and sometimes uncommon conditions, including anatomic conditions, such as hiatal hernias or structural anomalies. *Helicobacter pylori* gastritis as a cause remains a point of debate.^{31,32} Celiac disease can be a comorbid condition in various genetic syndromes.^{33,34} Behavioral characteristics, related to underlying pain or temperament differences, can be confused with GER. Eosinophilic esophagitis should be considered in the differential diagnosis, especially in

children not responding to appropriate reflux management.³⁵

It is important to also consider a primary underlying central nervous system injury in the differential. For example, a group of infants who had either perinatal injury or dysphagia without specific etiology were found to have high-intensity lesions in the lower pons and medulla and pontomedullary atrophy on MRI studies. This suggests that a vagovagal reflex, mediated by brainstem function, might contribute to the disturbed motility of the upper digestive tract in some children.¹³

Children who have genetic syndromes and other developmental disabilities often require elective surgeries for a variety of reasons, such as scoliosis, contractures, and hip dysplasia. Because of the hardware inserted, casts applied, or the required postsurgical positioning, their previous unique posture for feeding may be compromised. If this “natural posturing” previously served as compensation for occasional aspiration or as assistance in moving and swallowing a bolus of food or fluid, then the potential for postoperative pulmonary events can be increased. Preoperative planning by the surgeon, the pediatrician, the pediatric hospitalist, the family, speech or occupational therapists, and the dietitian allows for presurgical intervention to minimize such risks. Table 2 outlines some presurgical considerations.³⁶ On the basis of a holistic assessment, consideration of nonoral feeding for a period before surgery (for optimal nutritional stores and pulmonary status) and for a period postsurgery (for wound healing and airway safety) may be necessary.

Children in Palliative Care

Elements of ethical decision-making are recurring considerations in the daily and year-to-year care of children who have developmental or acquired

disabilities. Often, decisions are made without deliberate attention to conversations about prognostic or ethical implications. The Association for Children’s Palliative Care published a *Guide to the Development of Palliative Care Services*, which includes information about children who have developmental disabilities.³⁷ Some children receiving palliative care coordination may be in an imminent terminal-care stage; for others, the trajectory of deterioration may be months or longer. Because such prognostication can be difficult, special consideration and flexible planning for nutritional support is required.

In some circumstances, families and members of their support system may decide against further nonoral nutrition/hydration interventions.³⁷ Otherwise, nutritional support care plans should be devised (1) after identification of likelihood of risk for malnutrition (energy needs, nutrient needs, effects of medications, effects of underlying condition), (2) in concert with family, physicians, palliative care team, pediatric dietitians, and the speech pathologist monitoring oral-motor skills, (3) whenever

safe and possible, to allow continued oral nutrition (with preferences of the child considered), and (4) to maintain energy, minimize pain or irritability, and focus on overall (not just health-related) QOL goals. These care plans may vary over time because of activity, mobility, tone issues, fever fluctuations, skin integrity, or acute illnesses.

The terminal nature of conditions warranting palliative care intervention places a spotlight on many decisions relative to care and support. Decisions related to nonoral feedings—adjunctively or solely—require sensitive awareness of individual needs. To greater or lesser degrees, similar shared decision-making is needed for any child being considered for nonoral feedings.

SHARED DECISION-MAKING: A MULTIFACTORIAL PROCESS

Ultimately the concerns outlined previously are helpful signposts, but no single clinical finding in isolation is an absolute indication to avoid *all* oral intake and move solely to nonoral feedings indefinitely. Rather, the multiple components serve as discussion

TABLE 2 Considerations Before Surgical Procedures: Nutrition, Airway Safety, and Surgery: Considerations for Nonoral Feeding Intervention

Developmental disability with known dysphagia, airway concerns
Significantly underweight/failure to thrive
Pulmonary function and reactive airway disease: status and optimal management
Suboptimal nutrient status (calories/vitamins/micronutrients/protein/iron/other)
Medication–nutrient interaction
Cultural requirements for special or specific diets
Financial/insurance issues related to pre- or postoperative nutrition support
Formulas
Equipment
Nursing or personal care assistance
Postoperative supplements likely to be needed
Potential need for total parenteral nutrition
Peripheral venous access versus central
Energy needs
Baseline
Anticipated NPO status for planned procedure
Wound-healing support
Likelihood of repeat operating room procedures requiring NPO status
Oromotor feeding
Iatrogenic factors likely to impact feeding abilities
Postoperative pain management plan and nutritional considerations
NPO, no oral intake.

points for collaboration among the patient, the family, and the health care professionals.

Considering both the clinical status and the social contexts of the child, questions to be considered include:

- Do they support adequate caloric, nutrient, and fluid intake?
- Do they support optimal health-related quality of life (HRQOL)?
- Do they support optimal QOL?
- Are the present conditions optimal? Safe? Psychosocially and clinically sustainable?
- Do they allow a combination of oral and nonoral intake?
- Is the present situation temporary, or is it likely to be ongoing or progressive?
- Are potential changes in feeding methods and schedules *realistic* for the family?

An informed and sensitive approach is in order. This is best accomplished using a cross-discipline approach. After discussion with the patient and the family, these decisions can be direct and straightforward, exceedingly difficult, or somewhere along that spectrum.^{38,39}

Although families and professionals each use the term “quality of life,” this can be projected and/or perceived variably. Neither clinicians nor researchers have yet to agree on a universal definition of either QOL or HRQOL. For purposes of this article, the following are general descriptions:

- QOL: the overall sense of well-being, including aspects of happiness and satisfaction with life as a whole
- HRQOL: aspects of QOL that affect health (physical or mental) or are affected by health and that are associated with life satisfaction^{17,24}

Petersen et al described caregivers’ perceptions of nonoral feeding for children who have developmental disabilities.

Most of these perceptions were encapsulated in either the QOL or the HRQOL categories (suggested even in the article’s title, “Eating and Feeding are Not the Same”).⁴⁰ The complexities and contradictions in “coming to consensus” on this topic were nicely outlined with several concerns generated from families:

- Is the enteral feeding a confirmation of the permanence of the child’s disability?
- Will it increase discrimination and be viewed as additional stigma?
- Will it produce a loss of the nurturing, parental experience for the caregiver?
- Will it prevent “pleasure of eating” for the child?
- Will it prevent mealtime social associations?

Mahant et al⁴¹ conducted a qualitative systematic review of publications focused on the experiences of parents who had actively participated in the decision-making before initiation of nonoral feeding for their children who had neurologic disorders. The authors identified 3 major themes related to decision-making:

- Context: characteristics unique to the family, child, and the circumstances bearing on each
- Values: attitudes, beliefs, and belief systems affecting decisions regarding nonoral feedings for nutritional support
- Process: the perceived manner of decision-making in concert with health teams

Figure 1 offers a schematic of example factors contributing to *decisional conflict* or *decisional resolution* based on a modification of Mahant’s work. The outline supports the concept of shared decision-making to minimize conflict and enhance decisional resolution. For the pediatrician involved in

this process, Shakespeare’s words are a useful reminder: “The web of our life is of a mingled yarn, good and ill together.”⁴² How the terms “good” and “ill,” “quality of life,” “medically necessary,” “comfort,” and others are defined is unique to the family, the child, and the clinical situation. Unmingling the yarn requires time, sensitivity to the situation, and a knowledge base to provide information, support, and collaboration.

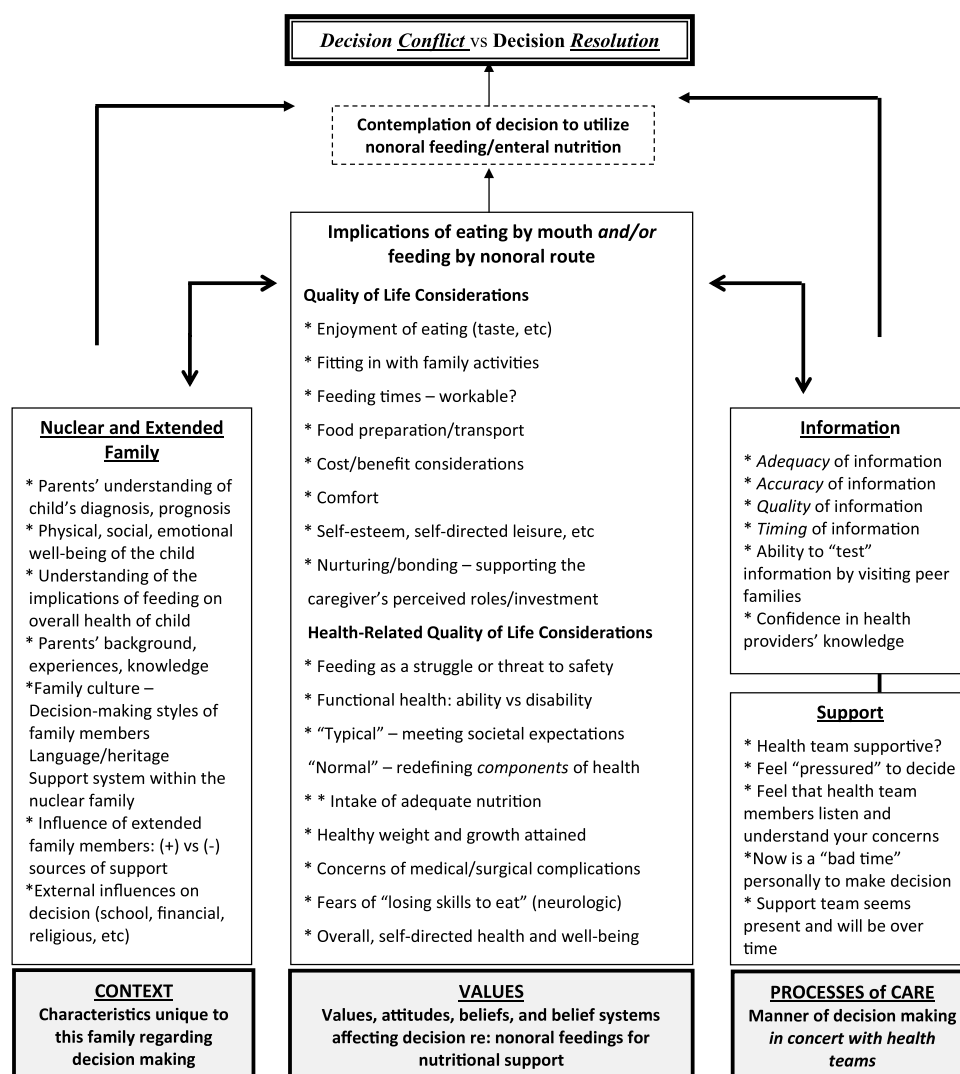
Beyond the emotional, social, cultural, or financial aspects of nonoral feedings, other clinical considerations include:

- Growth differences: growth failure, diminished growth trajectories
- Malnourishment⁴³
- Dysphagia and associated respiratory complications
- Skeletal problems or other comorbid conditions with links to nutritional concerns
- Neurologic conditions directly affecting gut motility and fecal evacuation
- Comfort, sleep, and behavioral issues manifesting in a poorly nourished child

Medical conditions resulting from or contributing to suboptimal growth and nutritional health should be assessed before recommending nonoral feedings. Table 3 lists laboratory and/or clinical evaluations that might be useful.

Once consensus is reached to go forward with adjunctive feedings for nutritional support, more options await the family and support team. Figure 2 offers a decision-tree approach to the information that follows.

When oral feeding is deemed insufficient for adequate nutrition, an early consideration is: “How long is the nonoral feeding regimen likely to be needed?” If the estimate is a relatively short period (<8 weeks), use of

**FIGURE 1**

Nonoral feeding and shared decision-making: resolution versus unresolved conflict (modified from Mahant⁴¹).

a nasogastric (NG) tube feeding regimen might be considered. If there is clinically significant preexisting GER, the alternative use of a nasojejunal (NJ) feeding tube may be advantageous. On the basis of the child’s primary and comorbid conditions, these tube feedings may be variably tolerated. Thus, families will need education on reinsertion of NG tubes; NJ replacement typically requires fluoroscopic guidance. The goal is resumption of oral feeding once the acute situation has resolved.

If adjunctive or total nonoral feedings are likely to be longer in duration,

consideration of a gastrostomy button (or tube) should be considered. This is particularly appropriate for the child who is engaged in a “typical” environmental schedule (eg, school, community, sports). For children who have ongoing need for nonoral feedings, the gastrostomy tube is better tolerated physically, socially, and functionally than NG or NJ tubes. Several types of approaches and equipment are available as options: (1) a percutaneous and endoscopic procedure for gastrostomy button insertion, (2) a surgically placed button (or tube) into the stomach, or (3) gastrojejunal tube insertion.

Advantages and constraints of the various methods of nutritional delivery should be a part of the shared decision-making process. For example, the family can “bolus” feedings (deliver an adequate-volume “meal” in a relatively short timeframe) via the NG tube or the gastrostomy button when GER or excessively delayed stomach emptying are not serious concerns. Alternatively, extended-time feedings are necessary when jejunal feedings are required.

Before placement of a gastric button in a child who has neurodevelopmental disorders, there should be

TABLE 3 Clinical Laboratory Tests and Other Clinical Studies That May be Useful Before Nonoral Feeding^a

Clinical Investigation	Specific Measures
Serum	Iron panel and serum ferritin Zinc; 25-OH vitamin D Protein/albumin Celiac panel Complete blood cell count and metabolic panel
Urine	Urine analysis
Imaging	Upper gastrointestinal tract study to rule out malrotation, other anomalies If clinically indicated, nuclear medicine gastric emptying study
Biopsy/scope	Eosinophilic esophagitis Celiac disease, gastritis

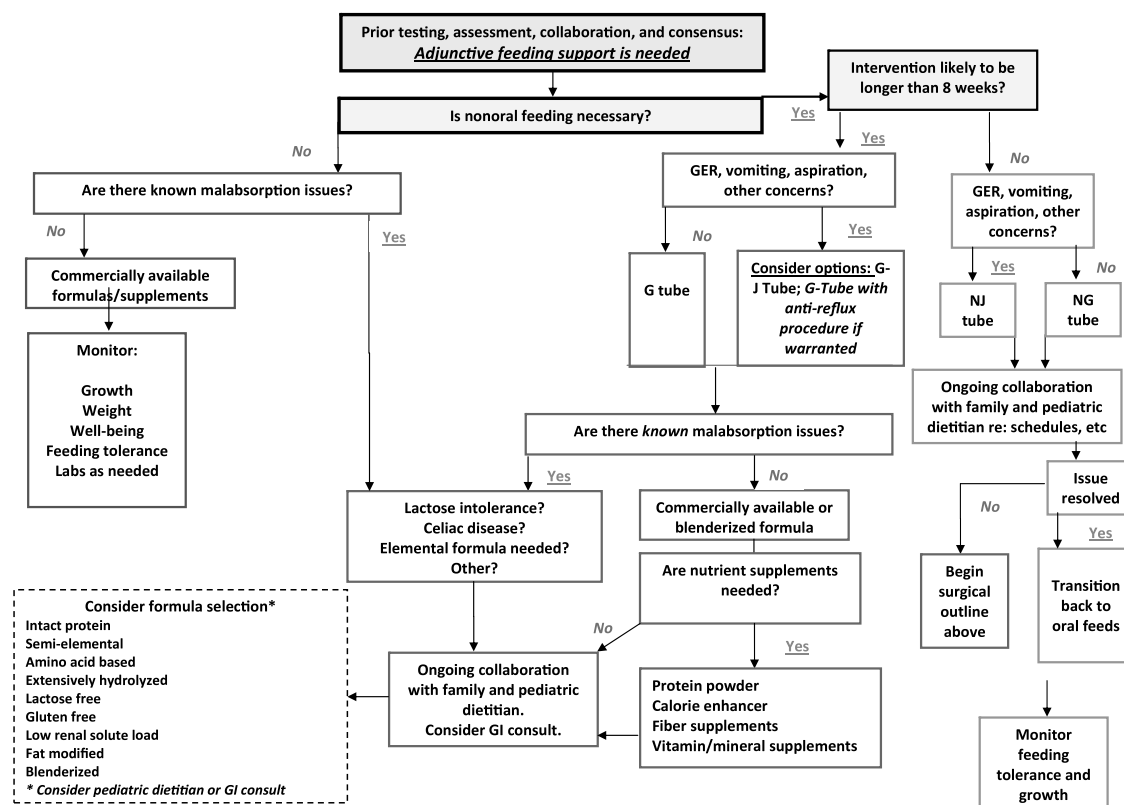
^a Investigations listed are meant as a guide for thoughtful consideration, not a standard of practice.

consideration of signs or symptoms of delayed gastric emptying. If emptying is somewhat slow, this can be improved through altering formula selection, volumes per feeding, schedule of feedings, or rate of feedings and with medications such as erythromycin or metoclopramide. If the emptying time is

significantly delayed and these considerations are not accounted for, the child remains at risk for emesis, discomfort, and potential aspiration.⁴⁴

Excluding decisions for nonoral feedings that are precipitated by acute severe medical/surgical/traumatic emergencies, the ultimate decision to move forward

with nonoral feedings can best be supported if the family has had a preceding and continuing relationship with a pediatric dietitian. Nutritional guidance and information sharing is central to the care of the child who has developmental or acquired disabilities; thus, the dietitian should be included in the core decision-making team. Micronutrient composition of formulas and the caloric requirements of the individual child vary; they require close monitoring and direction.^{45,46} Nutritional assessments periodically allow for earlier identification of the at-risk child. Having a preexisting understanding of the family's concerns and values provides greater credibility when more difficult conversations and decision-making are required.⁴⁷ A strong alliance between the pediatrician, the speech therapist, and pediatric dietitian—whether within the pediatric office or at a location for ready

**FIGURE 2**

Decisions in adjunctive feedings of the child/adolescent with developmental disabilities.

referral—best serves the families of children who have disabilities.

OUTCOMES STUDIES THAT INFORM DECISION-MAKERS

As families consider (1) surgical placement of a gastrostomy button as an adjunct to or for replacement of oral feedings, and (2) the advisability of a gastric fundoplication for comorbid GER, the need for best evidence of optimal outcomes arises. Studies of children and families have been published describing outcomes of gastrostomy tube placement and feeding. Although limited in scope and number, the outcomes provide the pediatrician and the families with some data for decision-making (Table 4). Extant literature suggests that if the decision points outlined previously are addressed and the medical needs are identified, the pediatrician can assure parents and children that the nonoral feeding option can be positive. This can be stated in regard to both physical *and* QOL considerations. Variances in adverse events point to the “operator-dependent” nature of the surgical procedures, to pre-existing comorbidities, and to supportive aftercare.

The psychosocial and emotional considerations in qualitative outcome studies emphasize the value of physician-to-parent and parent-to-parent support in decision-making regarding nonoral feeding. Conversations about what constitutes “normal” can help to alleviate an overwhelming sense of disappointment or guilt in going forward. “Normal nutrition” involves adequate fluid intake, adequate caloric and nutrient intake, achieving a sense of satiety, achieving typical growth patterns, safety in delivery of food (eg, avoidance of aspiration), and good health. Often these components are compromised in oral feeding of children who have disabilities but are improved with adjunctive and/or replacement nonoral feedings.

Support for the child and family should begin well before decision-making and placement of the gastrostomy tube. Protocols for educating and instructing families about the gastrostomy tube can inform the clinical decision process. Such protocols can include hands-on feeling of the devices, doll models for adults and children alike to better understand anatomy, drawings, and verbal reinforcement. This information is valuable early in decision-making, but reinforcement is needed in the months and years thereafter as the child grows and new situations require updating of feeding regimens.

Fundoplication Surgery

The need for antireflux intervention is a common topic as families consider gastrostomy tube placement. When pharmacologic and/or dietary interventions have been exhausted, a common surgical option is the Nissen fundoplication (or a modification). The goals of fundoplication include (1) restore the intra-abdominal esophagus, (2) restore the angle of His, (3) reconstruct the diaphragmatic hiatus (when necessary), and (4) reinforce the lower esophageal sphincter and increase basal lower esophageal sphincter pressure.⁴⁸

The value of fundoplication surgery with or without gastrostomy tube placement has, for decades, been a focus of debate and contradiction. To some degree, it remains so even now. When GER is highly suspected clinically before gastrostomy tube placement, evaluation by nuclear medicine, direct endoscopic visualization/biopsy, classic pH, or multichannel intraluminal impedance-pH studies are options for assessment.⁴⁹ Despite the advancement of technical methods of measuring esophageal parameters, ongoing lack of clarity remains as to the clinical relevance of the measurements and their predictive value after surgery.^{44,50-52}

Again, evidence-based outcome studies—limited as they are—provide an element of understanding when advising families. Unlike the studies on gastrostomy tube placement outcome, the data from studies related to fundoplication surgery fail to suggest which patients might be best suited for the procedure. For example, a study of reflux using multichannel intraluminal impedance-pH studies provides insight into the technical challenges in administering the examination, although the patients described excluded children who have overt neurologic disorders, metabolic disorders, or respiratory and/or gastrointestinal malformations.⁵³ In response to earlier suggestions for “the need for a ‘protective’ antireflux operation in children referred for feeding gastrostomy,”⁵⁴ Puntis et al provided data “in the child with neurological disabilities without symptoms indicating severe gastroesophageal reflux” and their conclusions that “fundoplication is unlikely to be necessary as a consequence of percutaneous endoscopic gastrostomy” and that the number of antireflux surgical procedures should be reduced.⁵⁵ Similarly, the outcome reports of variations in fundoplication techniques (eg, open, laparoscopic) offer differences in respective advantages and disadvantages.^{56,57}

A number of complications and adverse effects have been described and attributed to fundoplication surgery: alterations in gastric tone (perhaps related to injury of the vagal nerve at operation); *accelerated* gastric emptying (“dumping syndrome”); *delayed* gastric emptying after surgery related to vagal nerve injury; and retching (potentially related to visceral afferent sensitivity and vagal nerve injury). The gas bloating syndrome (inability to belch and vomit, abdominal pain after eating, and/or dysphagia) can result from 1 or more of these complications.

TABLE 4 Summary of Recent Outcome Studies Related to Gastrostomy and Nonoral Feeding

Reference	Subject	Comments
Craig et al, 2006 ⁸⁵	Medical, surgical, and health outcomes of gastrostomy feeding	Prospective study; before and after gastrostomy; 76 children with neurodevelopmental disabilities and families. Two thirds of those with severe weight issues before achieved mean weight-for-age ($P = .001$). Other health gains included reduction in drooling, decreased secretions, less vomiting, improved constipation. Thirteen children after surgery had a significant complication (eg, internal fistula, adhesions, bleeding).
Enrione et al, 2005 ⁸⁶	Medical and psychological experiences of family caregivers with children fed nonorally	Qualitative study addressing the caregivers of children with gastrostomy tube feedings and whether they had problems and/or concerns themselves. Questionnaires sent to 150 families (37 participated). Major psychosocial issues included: "I feel sad because my child is deprived of many social activities that involve eating"; "I feel depressed about not being able to feed my child by mouth," "In my absence, I have trouble finding (someone to) feed my child." Over the course of the year after surgery, the medical concerns became less and the ranking of psychosocial issues increased.
Mahant et al, 2009 ⁸⁷	Tube feeding and quality of life in children who have severe neurologic impairment	In general, caregivers reported a positive effect on the child's health, particularly with regard to feeding, administration of medications, and weight gain. Based on use of nonvalidated questionnaire that used visual analog scale. Procedure deemed "safe" and with "few major complications" by parent reports.
Martinez-Costa et al, 2011 ⁸⁸	Early decision of gastrostomy in children who have severe developmental disability	Structured telephone script allowed input from parents of 26 children with severe disabilities. Caregivers "showed high satisfaction (91%)" and 87% noted they would have decided earlier to go forward with gastrostomy "had they anticipated the outcome." Patient management and family dynamics (including the child) were noted to have "improved considerably."
Samson-Fang et al, 2003 ⁸⁹	Effects of gastrostomy in children who have cerebral palsy using the AACPDM method for evidence reports	This important review considered previous outcome studies from 1956 through 2002, offering historical perspective in addition to detailed descriptions of studies and outcomes. Generally, the report cited less than robust levels of evidence and the need for further well-designed studies. There was a general consensus (low levels of evidence) of gastrostomy placement being "helpful."
Sleigh and Brocklehurst, 2004 ⁹⁰	Effects of gastrostomy feeding in cerebral palsy: another systematic review	This evidence-based review from the United Kingdom resulted in findings similar to those of Samson-Fang in 2003 and encouraged further studies with higher levels of evidence.
Sullivan et al, 2004 ⁹¹	Impact of gastrostomy feeding on the quality of life of caregivers to children who have cerebral palsy	Although the purpose of gastrostomy placement is solely for the care and benefit of the child, the parents continue to act as the "partners in feeding." Caregivers of 57 children with cerebral palsy reported significant reduction in feeding times, increased ease of drug delivery, and reduced concern about their child's nutritional status. In concert with these findings, the caregivers reported (12 mo after gastrostomy placement), that they, themselves, had significant improvement in social functioning, mental health, energy/vitality, and general health perception.
Wilken, 2012 ⁹²	A qualitative meta-analysis of maternal emotional state after initiating tube feeding in their child	A review of 7 qualitative studies (1997–2007). Both oral and tube feeding have multiple meanings for parents and "signify more than obtaining an adequate nutritional intake." Decisions about gastrostomy tube placement are complex and often difficult. A significant percentage of mothers noted lack of support during the decision-making process. After the tube insertion, there was description of both relief and disappointment (in "giving in" to the nonoral feeding).

The onset of postsurgical dumping syndrome (which can be observed irrespective of presurgical gastric emptying time studies) has been reported.^{48,58} Treatment of this condition can be approached by use of thickeners, selective formulas, nutritional supplements to formula being used, and pureed feedings in addition to or rather than formula only.^{59–61} If dumping syndrome is suspected and/or sustained, consultation with a gastroenterologist for formal diagnosis and collaborative treatment plans should be considered. Thus, on the broad question of “Is my child a good candidate for fundoplication?” recent clinical studies and reviews leave physicians and families very much where they have been for decades: fundoplication for the control of GER in children needs further evaluation.^{62,63} Given the lack of strong data from outcome studies with high levels of evidence, the decision for or against fundoplication at the time of gastrostomy tube placement remains a highly individual judgment. The severity of the reflux and its effects on the child, the response to previous vigorous medical treatment of GER, the outcome experiences of and opinion of the pediatric surgeon (relative to fundoplication procedures), and comorbid medical/developmental conditions (ie, tracheotomy) are examples of components in the decision-making process. Qualitative studies and those focusing on HRQOL generally reflect a positive experience for the child and family after fundoplication.^{64–66}

POSTOPERATIVE SUPPORT AND COLLABORATIVE CARE

Although the choice for surgery can be considered a “landmark” decision, ongoing medical and psychosocial support is needed for an extended period after the procedure. This follow-up is best provided in the context of a collaborative commitment involving family,

pediatrician, and colleagues, such as the dietitian, speech pathologist/occupational therapist, and social worker. Collaborative care is outlined in 3 categories: (1) the roles of professionals and caregivers, (2) care of the gastrostomy tube and skin site, and (3) coordination of oral and nonoral feeding goals.

Roles of Pediatrician, Pediatric Dietitian, and Caregivers

For families, the process of surgery, equipment procurement, formula prescriptions and delivery, and ongoing care can become fragmented and problematic. Gordon et al described the value (emotional, financial, and medical) of a closely interconnected partnership between the tertiary care providers (such as developmental pediatric dysphagia teams) and the primary care physician for medically complex and fragile children who have special health care needs. Particularly valued by families was having a single “point professional” (eg, nurse, coordinator) at the primary care office and at the tertiary care center as their portals of entry; likewise, having those 2 resources in communication was deemed important.⁶⁷

On some periodic basis, specific inquiry of the family as to how the feedings are going provides an opportunity to acknowledge the long-term decision and to gather answers to specific questions/concerns about the process: effect on siblings; time and scheduling of feedings if different from other family members; need for advocacy relative to agencies, schools, child care facilities, or other; description of typical day and night schedule; most difficult aspect of the nonoral feeding at particular times (if any); level of perceived well-being by the primary caregiver(s); and any effects (positive or negative) on the child's social activity and participation.^{68–70}

Medical considerations for the long-term include monitoring for multiple

associated conditions in many ways similar to those focused on before surgery^{10,71,72}:

- Undernutrition, overweight, micronutrient deficiencies, food allergy-associated eosinophilic esophagitis
- Dental (gum and teeth) health status
- Medication changes from other subspecialists (eg, seizure medications)
- Pulmonary status and sleep status and their potential relationships to feedings
- Changing body structure (eg, scoliosis, osteopenia)
- Changing body function (eg, strength, tone, gut motility, oral motor dysfunction)
- Skin health, particularly around the gastrostomy tube site

The Pacific West Maternal & Child Health Distance Learning Network – CSHCN Nutrition (http://depts.washington.edu/chdd/ucedd/ctu_5/pacwestcshcn_5.html) offers a series of modules on nutrition for children who have special needs that are clinically relevant and supportive to the primary pediatrician.

The Academy of Nutrition and Dietetics has created “Standards of Practice and Standards of Professional Performance for Register Dietitians (Competent, Proficient, and Expert) in Intellectual and Developmental Disabilities.” Dietitians who have met criteria for “proficient” or “expert” in this field can be a remarkable resource to families and physicians alike when addressing ongoing clinical issues of nonoral feedings: construction of long-term nutrition plan; integration of feeding into home, skilled nursing, or school settings; updating feeding needs; problem solving (mealtime supports, technical feeding issues, communication skills of the child, changing levels of interdependence); advocacy with supporting agencies; and monitoring of nutritional status over time.^{23,36,73} See example forms

in Figs 3 and 4 for use in supporting families.

Care of Gastrostomy/Gastrojejunal Tube

Even if the care of the gastrostomy tube and associated conditions are managed mostly through the tertiary care center, the family is well served by the primary medical home that is familiar with care and maintenance of the gastrostomy button. For the pediatrician, helpful resources include:

- http://www.vygon.co.uk/pdf/upload/Enteral_Feedingfull.pdf
- <http://emedicine.medscape.com/article/149589-overview>
- <http://www.slideshare.net/jessicalynn-smith/finalpresentation-13485393>

These tutorials provide information on types of feeding tubes, stoma site care, tube maintenance, tube removal and replacement, and tips for problem solving. Beginning in 2014, a global initiative began to institute a unified set of industry standards for safer connectors that ensure compatibility and reduce the likelihood of tubing misconnections in enteral feeding systems.

Differences remain among pediatricians and surgeons as to their personal preferences for gastrostomy button replacement: some set a particular calendar schedule; others suggest a change only when the current button is faltering. Regardless, families should have available at all times either a spare button or Foley catheter (same diameter size as button) for unexpected loss of the gastrostomy button. If an emergency department or medical office is not immediately available, the family should know how to replace 1 of these until they can be seen by a medical professional.

Incorrect medication delivery through the tube can result in clogged tubes, decreased drug delivery, and/or drug-formula incompatibilities (particularly

common: phenytoin, carbamazepine, fluoroquinolones, and proton pump inhibitors). Most medications should not be added into the enteral formula bag. Medications need to have the tubing line flushed with warm water before and after dosing. If in question, consultation with a pharmacist will inform as to which medications can be crushed and used in which vehicle liquids.^{74,75}

Many times, the “venting tube” (or “burping tube”) that accompanies the replacement gastrostomy button kit is a highly valuable tool. For children who air-swallow and whose gastric air collection is interfering with feeding (bloating, distention, discomfort), use of the venting tube before and after feeding can ease these symptoms considerably.

Generally, the stoma site should be washed and cleansed as is the remainder of the chest and abdomen: washed with a pH-balanced bath soap, then left uncovered for access to open air. For the occasions when the site allows leakage, an absorptive wound care foam dressing will “wick” the moisture away from the skin more efficiently than cotton gauze pads.

The development of overgranulation tissue at the stoma site is not uncommon. The specific etiology of its development is not known, but several contributing factors have been suggested: reaction to a foreign body, undue pressure, repeated “trauma” or friction to the area, or excessive moisture to the area. An excellent literature review and subsequent care pathway to evaluate and manage overgranulation was provided by Warriner and Spruce⁷⁶; suggestions included:

- Silver nitrate applications have historically been used, but care must be taken to avoid damage to the tube, damage and pain to surrounding skin, and potential for further tissue damage or secondary infec-

tion at the site of the granulation tissue.

- Topical use of low-dose steroids has been evaluated; a specific tape (Haelen tape) impregnated with an appropriate steroidal preparation has been shown to be effective.^{77,78}
- If persistent, therapies used in wound care centers can be applied.
- If aggressive topical therapies are not eliminating the tissue and it is considered to be a problem (eg, bleeding, drainage onto clothing, odor, aesthetic), removal and replacement of the button/tube can sometimes help.

In the child whose dysmotility or reflux symptoms are being managed by use of a gastrojejunal tube rather than by gastrostomy and fundoplication procedure, its replacement generally requires fluoroscopy with the assistance of interventional radiologists. Migration of the gastrojejunal tube's tip from the intestine back into the stomach can result in regurgitation and aspiration. If suspected, feedings should be halted; consultation with the physician is warranted. Radiographic evaluation and tube replacement may be indicated.⁷⁹

Given the relatively small apertures in the jejunal tip of the tube, consideration of medications being delivered and formula additives being used is needed to avoid occlusion of the distal tip. It is often best to use the gastric port for medications. Clinical reports of bloating, cramping, and/or significant changes in fecal consistency warrant a review with the dietitian about volumes, rates, and osmolality of the formula being used.

Coordination of Oral and Nonoral Feeding Goals

For some, nonoral feedings are designed to be adjunctive to ongoing oral feedings. Depending on the medical circumstances that resulted in the

RE: Patient's Name
 DOB: 1/1/1111

To Whom It May Concern:

The Pediatric Developmental Disabilities team at Texas Scottish Rite Hospital for Children follows *Patient's Name*. Her diagnoses include *specific syndrome*, severe scoliosis, pectus excavatum with surgical repair x2, multiple cardiac issues, gastroesophageal reflux, asthma, and multiple pneumonias. She underwent gastrostomy placement on Jan 1, 2005, so that she may receive nonoral feedings to help her gain weight and improve her nutritional status in preparation for her upcoming scoliosis surgery.

Her most recent anthropometrics obtained on 1/16/14 were 150 cm (20th percentile/age) and 21.9 kg (<5th percentile/age). Her calculated BMI is 9.7, which is significantly below the 5th percentile for age.

Patient's Name needs a 1.5 kcal/cc formula to provide maximum calorie intake in minimal volume in addition to her oral feedings. Resource Just for Kids 1.5 w/fiber has been well tolerated by the patient. Three boxes daily will provide *Patient's Name* 1065 kcal/day (49/kg) to meet approximately 67% of her calorie needs.

Since *Patient's Name* is an active child with multiple activities and requires medical appointments, we are requesting an *XYZ Feeding Pump*. The following reasons outline why this is a unique and clinically necessary for our patient:

- 1.) **Accuracy:** The XYZ performs with a +/-5% accuracy with all solutions, across the full flow rate range.
- 2.) **Rate and dose selectivity:** The XYZ is the only enteral pump that can deliver nutrition solutions at rates as low as 0.1 mL/hour and as high as 600 mL/hour. It is also the only pump with programmable doses as low as 0.1 mL and as high as 3000 mL. *Programming flexibility allows for adjustments to the patient's therapy as needed.*
- 3.) **Battery life:** The XYZ twenty-four hour battery life capacity far exceeds any other pump. It is the only pump with a Lithium battery. A lightweight battery with long life *improves adherence with the needed feeding schedule.*
- 4.) **Portability:** The XYZ pump and disposable sets allow successful placement in custom packs or tote bags, at the bedside, on strollers, or on wheelchairs. The XYZ weighs less than 1 pound (about the weight of a can of soup) and has, by far, the smallest sized carrying pack options for pediatric and adult patients. In addition, the XYZ was designed to operate in any orientation. Many pumps require the use of a drip chamber in their disposable sets. This means they can only operate in the upright position. Patients rarely operate in an upright position. This combination of features enables health-improving physical activity.
- 5.) **Occlusion safety:** The XYZ is the only pump with upstream and downstream occlusion sensors to identify back pressure from the gut and clogged tubing. The downstream occlusion sensor is designed to alarm at a lower setting than any other pumps, specifically for the protection of pediatric patients.
- 6.) **Air alarm safety:** The XYZ is the only pump with an air detector, which detects air in the line. This protects sensitive patients from the infusion of air, which can lead to painful distention of the stomach or intestines.
- 7.) **Disposable set safety:** The XYZ disposable sets are entirely DEHP free and contain an in-line occluder, which will not allow solution to free flow into the patient if it is not loaded properly into the pump.
- 8.) **Cost savings:** The XYZ is a rugged pump designed for day-to-day handling. New sensing technology has allowed the pump to be completely sealed so it is the only pump washable under running water. In addition, it does not require annual maintenance/calibration.
- 9.) **Physical, social, and psychological benefits:** Based upon its unique feature set, the quality of life of the patient, the family, and caregiver are greatly improved by using the XYZ. The portability and ease of use features of the XYZ remove significant barriers to health-improving physical activity, allowing adults to return to work, and social interaction of patients with friends and family.

We are requesting insurance funding for the following:

- (1) XYZ ambulatory feeding pump
- (2) IV pole
- (3) XYZ 500-mL feeding bags, 30/month
- (4) Formula type 1.5 w/fiber, 750 ml (3 boxes) daily
- (5) Farrell valve gastric relief bags, 30/month
- (6) Brand g-button replacement, 2/year
- (7) Brand extension sets, 4/month
- (8) 60-mL syringes, 5/month
- (9) 10-mL syringes, 5/month

Your assistance to the family will be greatly appreciated. If further details are required, please do not hesitate to contact the dietitian at (555) 555-5555.

Sincerely,

Richard C. Adams, MD, FAAP

Wendy Wittenbrook, MA, RD, CSP, LD

FIGURE 3

Sample letter of support to assist families.

TEXAS SCOTTISH RITE HOSPITAL FOR CHILDREN 2222 WELBORN ST DALLAS, TEXAS 75219 PHYSICIAN'S GASTROSTOMY DIET ORDER MEDICAL STATEMENT FOR STUDENTS WITH SPECIAL DIET NEEDS	DATE: _____ TIME: _____
Diagnosis: <u>Gastrostomy</u> ALLERGIES: _____	
☐ Patient receives no po feedings ☐ Patient also receives po feedings (<i>see additional orders</i>) ☐ Tube Feedings	
Formula: _____ (<i>or equivalent</i>) Number of daily feedings: _____ Schedule: _____ (<i>may vary by up ½ hour to meet school schedule</i>) Amount of formula at each feeding: _____	
Infuse formula via: ☐ Gravity drip over a period of _____ minutes ☐ Bolus feed with a syringe over a period of _____ minutes ☐ Feeding pump at a rate of _____ ml/hr	
After each feeding, rinse the G-tube with _____ ml water ☐ Vent/burp G-tube prior to each feeding. ☐ Use Farrell valve bag during feedings. ☐ Feed _____ ml water _____ times daily at _____	
DO NOT check residuals if a child has a gastrostomy button. If the tube dislodges or problems occur during feeding, discontinue feedings and notify the parents(s)/Developmental Pediatrics Department at Texas Scottish Rite Hospital.	
☐ Additional instructions: _____ _____ _____ _____	
Clinical Dietitian Signature: _____ Physician Signature: _____ Phone number: _____ Date: _____	
<i>Original on chart; copy to parent</i>	
Physician Orders	

FIGURE 4

Sample letter: orders for school.

need for nonoral feedings, some children will be able to later resume full oral feedings and ultimately remove the gastrostomy button. For these children,

the gastrostomy button is placed with plans for its eventual removal. For many children who have complex neurodevelopmental disabilities, the

likelihood of the gastrostomy use (solely or in combination with some oral intake) for extended times is high. To the extent that oral-motor coordination skills allow,

oral feeding can assist in dental health, maintenance of feeding skills, enjoyment, and social considerations.

Video-fluoroscopy feeding studies (modified barium swallows) are helpful in discriminating between “safe” foods and textures that can be maintained by mouth and “unsafe” textures and foods that place the child at risk for acute or chronic pulmonary conditions. By removing the “high risk” foods, the child can become less defensive (protective) of materials entering the mouth and, thereby, increase the ease and comfort of oral feeding. Repetitive fluoroscopy studies, too often based on arbitrary periodicity schedules, should not be considered a clinical requirement. The radiation exposure from an individual study is acceptable, but frequent or repeated exposures are concerning and should be guided by clinical risk/benefit considerations. Fiber optic endoscopic evaluation of swallowing offers direct visualization of anatomic pharyngeal structures during swallowing, but does not provide information about the oral phase of dysphagia or predict long-term feeding status in children.⁸⁰

Programs focused on establishing “normal” eating behaviors in children can be successful. However, it is important to understand the nature of the programs, their goals and methods, and subject selection (feeding issues among the children treated).^{81–83} For example, in 1 university-based program, the eligible children met specific criteria: resolution or stability of the medical problem causing the need for fundoplication; absence of anatomic or functional impairment precluding safe oral feeding; absence of oral-motor apraxia; maintenance of adequate weight on gastrostomy tube feedings; and/or cognitive/developmental status adequate to allow a response to behavioral therapy sessions.⁸⁴

When transition back to full oral feedings is being considered, several

questions can help guide the discussion:

- Is the child presently showing adequate growth trends?
- Have oral skills and swallow coordination and safety been recently assessed, preferably by an interdisciplinary dysphagia team?
- Has the medical condition that precipitated the need for the nonoral feeding been corrected or significantly improved?
- Are adequate professional resources (eg, speech therapist with background in feeding children who have disabilities, supports within the school setting, home supports) available to the family in the transition process?
- Are significant child behavioral issues present that could disrupt a transition plan? As the child grows and social constraints of feeding are recognized, psychosupportive therapy may be helpful in this phase of his or her “adjustment to disabilities.” New strategies for coping and interacting with peers and with others in the community may require focused cognitive behavioral therapeutic approaches, especially if the likelihood of nonoral feeding is ongoing.

CONCLUSIONS

The decision to begin nonoral feedings for a child who has acquired or developmental disabilities is complex. Aspects of medical care, cultural values and beliefs (of both the family and the health care professionals), and emotional investments deserve consideration. A commitment to surgery and nonoral feedings involves active dedication by the family, physicians, caregivers, dietitians, social workers, and others involved with the child’s care. This commitment is needed in the process of coming to a decision,

taking action on the decision, and especially after a surgical procedure. Optimal function, health, quality of life, safety, comfort, and care should be underlying components driving collaborative plans and support of the child.

RESOURCES FOR MEDICAL HOMES

- <http://www.slideshare.net/jessicalynsmith/finalpresentation-13485393>. Medical and nutritional management of feeding orders; differential diagnosis and care
- <http://www.oley.org/>. Oley Foundation; not-for-profit foundation. Information for clinicians, clients, and families
- http://depts.washington.edu/chdd/ucedd/ctu_5/pacwestcshcn_5.html. Nutrition for children with special health care needs: 4 group study modules
- http://www.cpresearch.org.au/pdfs/pw_tr_Alternatives_to_Oral_Feeding.pdf. Cerebral Palsy Alliance site with focus on nonoral feeding
- <http://www.nature.com/gimo/contents/pt1/full/gimo17.html>. Contains copy of overview information from Arvedson JC. Swallowing and feeding in infants and young children. *GI Motility Online*. Published online May 16, 2006.
- http://www.vygon.co.uk/pdf/upload/Enteral_Feedingfull.pdf. Practical care and maintenance of stoma sites and feeding tubes
- <http://www.readbag.com/seattle-childrens-pdf-pe442>. Information on preparing home blenderized food for gastrointestinal tube use

RESOURCES FOR FAMILIES

- <http://www.our-kids.org/>. Parent-guided Web site
- <http://www.complexchild.com/>. Online magazine written by parents of children who have complex care needs

- <http://www.oley.org/>. Oley Foundation, a nonprofit organization addressing needs of individuals who have non-oral feeding

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Off-Label Use of Drugs in Children

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- *Policy Statement*

POLICY STATEMENT

Off-Label Use of Drugs in Children

COMMITTEE ON DRUGS

KEY WORDS

off-label drug use, pharmaceuticals, pediatrics, infants, children, adolescents, prescribing

ABBREVIATIONS

BPCA—Best Pharmaceuticals for Children Act

FDA—US Food and Drug Administration

PREA—Pediatric Research Equity Act

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abstract

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The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than 500 labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term “off-label” does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. *Pediatrics* 2014;133:563–567

INTRODUCTION

The purpose of this statement is to further define and discuss the status of off-label use of medications in children. Since publication of the 2002 statement from the American Academy of Pediatrics on the off-label use of drugs,¹ the number of drugs approved by the US Food and Drug Administration (FDA) with pediatric indications or expanded labeling that informs drug use in pediatric patients (eg, pharmacokinetic/pharmacodynamic data, safety data) has substantially increased. The passage of the Best Pharmaceuticals for Children Act² (BPCA) and the Pediatric Research Equity Act³ (PREA) has resulted in more than 500 pediatric labeling changes. However, despite this success and advances in both basic science and clinical trials in pediatrics, off-label drug use remains a common and important issue for children and adolescents. Moreover, off-label use of drugs presents an even larger and more complex issue in preterm and full-term neonates, infants and in children younger than 2 years,⁴ and children with chronic and/or rare diseases.

DEFINING OFF-LABEL USE

The term “off-label” use refers to use of a drug that is not included in the package insert (approved labeling) for that drug. The purpose of off-label use is to benefit an individual patient. It is important to note that the term “off-label” does not imply an improper, illegal, contraindicated, or investigational use. To approve a drug for sale and marketing within the United States, the FDA requires substantial

evidence for efficacy and safety, usually in the form of 2 well-controlled trials. Subsequent requests by a sponsor to add a new indication to drug labeling must also be accompanied by additional evidence in support of that indication. If the FDA finds that such evidence supports approval, the new indication is added to the product labeling. If the evidence is deemed insufficient or if the sponsor chooses not to submit evidence, the indication is not added.

According to the Code of Federal Regulations,⁵ a sponsor is the entity that holds an investigational new drug application and that both takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. A sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual who uses 1 or more of his or her own employees to conduct an investigation that he or she has initiated is considered to be a sponsor, not a sponsor-investigator. In this case, the employees are investigators. Sponsor-investigators both initiate and conduct an investigation and direct the administration or dispensing of the investigational drug. The requirements applicable to a sponsor-investigator include both those applicable to an investigator and a sponsor. It is important to note that sponsors are not allowed to promote or even speak to off-label use. If a physician speaks on behalf of a sponsor, the same rule applies. It is acceptable to use drugs off label and to publish results related to off-label use, but it is not acceptable to receive remuneration from the sponsor for these uses.

The absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the

drug's use is improper for that age or disorder. Rather, it only means that the evidence required by law to allow inclusion in the label has not been approved by the FDA. Additionally, in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children. Instead, it specifically means that evidence for drug efficacy and safety in the pediatric population has not been submitted to FDA for review or has not met the regulatory standards of "substantial evidence" for FDA approval. In contrast to the absence of pediatric-specific information on some medications, other drug labels contain statements such as "the safety and efficacy in pediatric patients have not been established," and explicit evidence-based warnings and contraindications are included on the label where indicated. Understanding the distinction between the lack of FDA approval for a particular use or dosing regimen in the former case versus explicit warnings or contraindications against use in the latter is essential for the pediatric practitioner. In addition, when considering best practices for therapeutic decision-making, it is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine.⁶

THE ROLE OF THE FDA

The FDA is the federal government agency charged with oversight responsibility for the manufacturing, labeling, advertisement, and safety of therapeutic drugs and biological products. The Food, Drug, and Cosmetic Act⁷ requires that "substantial evidence," resulting from "adequate and well-controlled investigations" demonstrating that a new drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," be submitted to and reviewed and approved by the FDA

before the drug is marketed in interstate commerce. For drugs and biological agents (eg, vaccines, antibodies), proof of effectiveness consists of "adequate and well-controlled studies" as defined for new drugs in the Code of Federal Regulations.⁸ Biological agents are approved under the Public Health Service Act.⁹ Given these requirements as well as the rapid pace of medical discovery, it is not surprising that labeling does not reflect all possible uses of an agent. Off-label use of drugs in children is not overseen by the FDA, because the FDA does not regulate the prescription practices of individual practitioners.

The FDA maintains a system for post-marketing drug surveillance, compiling and analyzing information about the incidence and severity of adverse events reported by practitioners, sponsors, hospitals, and other health care facilities. It is important to note that this postmarket surveillance system is passive and that the total number of adverse event reports in pediatrics relative to adults is small. To address this issue, the BPCA provides for a systematized review of adverse event reports in pediatric patients through the FDA Pediatric Advisory Committee. When the FDA notes an apparent association between use of a drug and an adverse event, the FDA may choose from several actions: to request further focused study of the drug, to add a contraindication or warning to the drug labeling, to issue a warning about use of the drug, or to seek voluntary or compulsory removal of the drug from the market. Therefore, although the FDA does not regulate the practice of medicine, practitioners should be aware of new information brought forward by the FDA, because it can serve as a valuable resource for information regarding the potential or proven adverse effects of drugs (see www.fda.gov).

THERAPEUTIC DECISION-MAKING

Therapeutic decision-making should always be guided by the best available evidence and the importance of the benefit for the individual patient. Practitioners are in agreement regarding the importance of practicing evidence-based medicine. However, for the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice. There are now many resources available to help assess the quality of evidence-based medicine, including but not restricted to articles in peer-reviewed journals, American Academy of Pediatrics practice guidelines and policy statements, consensus statements, and handbooks and databases (ie, Cochrane, Lexicomp, and Harriet Lane). At times, there may be little or no published information to guide therapy. This situation is especially true when treating rare diseases or sparse populations such as neonates. In such situations, the practicing physician can play an important role in adding to therapeutic information by publishing his or her experience with off-label uses of drugs. These reports can serve as the basis of more formal efficacy and safety studies and can serve as a therapeutic decision-making resource for other physicians. The practicing physician also has a responsibility to report adverse events to the FDA through the Medwatch program (www.fda.gov/Safety/MedWatch).

In most situations, off-label use of medications is neither experimentation nor research. The administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest.⁶

In general, if existing evidence supports the use of a drug for a specific indication in a particular patient, the usual informed-consent conversations should be conducted, including anticipated risks, benefits, and alternatives. If the off-label use is based on sound medical evidence, no additional informed consent beyond that routinely used in therapeutic decision-making is needed.¹⁰ However, if the off-label use is experimental, then the patient (or parent) should be informed of its experimental status.¹¹ It would be prudent for pediatricians to know and abide by the appropriate informed consent laws in their respective states. In addition, particular risk-benefit ratios presented by the unproven therapies must be carefully considered and disclosed, and standard of care practices should be reviewed. When use of a drug is truly investigational, drug use should be performed in conjunction with a well-designed clinical trial whenever possible. This is especially true when the physician proposes to treat a group of patients rather than a single individual. Patients and/or their legal guardians should be specifically informed that the proposed therapy is investigational, and their consent to proceed despite the risks of investigational therapy should be carefully documented. Whether institutional review, consultation, or written consent are required for a given intervention depends on the degree of risk or departure from standard practices and the extent to which research, rather than individual patient care, is involved.

Practitioners may be concerned that the off-label use of an approved drug may invite a variety of legal actions. To conform to accepted professional standards, the off-label use of a drug should be done in good faith, in the best interest of the patient, and without fraudulent intent. A practitioner

may be accountable for the negligent use of any drug in a civil action, regardless of whether the FDA has approved the use of that drug. Labeling is not intended to preclude the practitioner from using his or her best medical judgment in the interest of patients or to impose liability for off-label use. Indeed, the practice of medicine will more than likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient. However, because the use of drugs in an off-label capacity can increase the liability risk for a practitioner should an adverse event or poor outcome ensue, it is essential that practitioners document the decision-making process to use a drug off label in the patient's medical record.

FEDERAL LEGISLATION TO INCREASE DRUG TESTING IN CHILDREN

The BPCA and the PREA are 2 complementary federal laws that have substantially increased clinical evaluation and labeling of drugs in children both by the pharmaceutical industry and through government-sponsored trials.⁸ The PREA mandates that almost all new drugs and certain approved drugs must be studied in children for approved uses of the product if there is potential for use of that drug in children and that the application for new drug approval include the results of adequate pediatric studies unless the studies are deferred or waived by the FDA. The BPCA allows sponsors to qualify for an additional 6 months of market exclusivity if the sponsor completes and submits pediatric studies to the FDA, as outlined in an FDA-issued written request. A written request may include off-label as well as approved uses of a drug. In addition, the BPCA authorizes the National Institutes of Health, in conjunction with the FDA

and physicians from clinical disciplines, to work together to assign priority for testing of specific drugs in children. The National Institutes of Health, acting through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, then solicits proposals for pediatric drug testing concordant with the drug prioritization recommendations and funds clinical studies that are judged meritorious by external review. The ratification of these 2 laws has been considered a significant success, because there have been more than 500 pediatric labeling changes. Also as a result of these laws, increased prospective pediatric drug testing has occurred via industry-sponsored studies, investigator-initiated studies, and consortia, such as the National Institute of Child Health and Human Development–funded Pediatric Trials Network. The net result has been an expansion of both pediatric labeling information and the knowledge base from which practitioners can draw to make informed therapeutic decisions.^{12,13}

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act,¹⁴ reauthorizing and strengthening the BPCA and PREA. The legislation aims to ensure that pediatric evaluations under PREA are conducted earlier in the drug development process to improve the quality of and accountability for completion of such studies and to advance the neonatal drug studies under the BPCA and PREA. The legislation also makes both the BPCA and PREA permanent law.

CONCLUSIONS

Off-label drug use remains an important public health issue, especially for infants, young children, and children with rare diseases. Evidence, not label indication, remains the gold standard from which practitioners should draw

when making therapeutic decisions for their patients. The PREA and BPCA have been extremely successful and represent an essential first step in expanding this evidence as a means of achieving the ultimate goal that any and all drugs used to treat children will have age-appropriate evidence sufficient to provide information for labeling. However, labeling with pediatric information still exists in less than 50% of products,¹⁵ such that much work remains to be done to ensure the best possible practice for therapeutic decision-making in pediatrics.

RECOMMENDATIONS

1. The practitioner who prescribes a drug is responsible for deciding which drug and dosing regimen the patient will receive and for what purpose.
 - a. This decision should be made on the basis of the information contained in the drug's labeling (when available) or other data available to the prescriber.
 - b. The use of a drug, whether off or on label, should be based on sound scientific evidence, expert medical judgment, or published literature whenever possible.
 - c. Off-label use is neither incorrect nor investigational if based on sound scientific evidence, expert medical judgment, or published literature.
2. Pediatricians should continue to advocate for necessary incentives and requirements to promote the study of drugs in children.
3. Physician researchers are encouraged to continue the rational and critical study of drugs in children through conducting and/or collaborating in well-designed pediatric drug studies, including national consortium studies.

4. Journals should be encouraged to publish the results of all well-designed investigations, including negative studies.
5. Institutions and payers should not use labeling status as the sole criterion that determines the availability on formulary or reimbursement status for medications in children. Similarly, less expensive therapeutic alternatives considered appropriate for adults should not automatically be considered appropriate first-line treatment in children. Finally, off-label uses of drugs should be considered when addressing various drug-related concerns, such as drug shortages.

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Optimizing Bone Health in Children and Adolescents

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- *Clinical Report*

CLINICAL REPORT

Optimizing Bone Health in Children and Adolescents

Neville H. Golden, MD, Steven A. Abrams, MD, and
COMMITTEE ON NUTRITION

KEY WORDS

calcium, dual-energy x-ray absorptiometry, DXA, osteoporosis, pediatrics, vitamin D

ABBREVIATIONS

1,25-OH₂D—1,25 dihydroxyvitamin D
25-OH-D—25-hydroxyvitamin D
AAP—Academy of Pediatrics
BMC—bone mineral content
BMD—bone mineral density
DMPA—depot medroxyprogesterone acetate
DXA—dual-energy x-ray absorptiometry
IGF-1—insulin-like growth factor 1
IOM—Institute of Medicine
PTH—parathyroid hormone
RDA—recommended dietary allowance

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

This clinical report has been endorsed by American Bone Health, a national, community-based organization that provides education programs, tools, and resources to help the public understand bone disease and bone health.

abstract

FREE

The pediatrician plays a major role in helping optimize bone health in children and adolescents. This clinical report reviews normal bone acquisition in infants, children, and adolescents and discusses factors affecting bone health in this age group. Previous recommended daily allowances for calcium and vitamin D are updated, and clinical guidance is provided regarding weight-bearing activities and recommendations for calcium and vitamin D intake and supplementation. Routine calcium supplementation is not recommended for healthy children and adolescents, but increased dietary intake to meet daily requirements is encouraged. The American Academy of Pediatrics endorses the higher recommended dietary allowances for vitamin D advised by the Institute of Medicine and supports testing for vitamin D deficiency in children and adolescents with conditions associated with increased bone fragility. Universal screening for vitamin D deficiency is not routinely recommended in healthy children or in children with dark skin or obesity because there is insufficient evidence of the cost-benefit of such a practice in reducing fracture risk. The preferred test to assess bone health is dual-energy x-ray absorptiometry, but caution is advised when interpreting results in children and adolescents who may not yet have achieved peak bone mass. For analyses, z scores should be used instead of T scores, and corrections should be made for size. Office-based strategies for the pediatrician to optimize bone health are provided. This clinical report has been endorsed by American Bone Health. *Pediatrics* 2014;134:e1229–e1243

The antecedents of osteoporosis are established in childhood and adolescence, and the pediatrician plays a major role in helping optimize bone health in the pediatric age group. Osteoporosis, a disease of increased bone fragility, is a major cause of morbidity and economic burden worldwide. It is estimated that by the year 2020, one-half of Americans older than 50 years will be at risk for osteoporotic fractures.¹ Once thought to be an inevitable part of aging, osteoporosis is now considered to have its roots in childhood, when preliminary preventative efforts can be initiated. In fact, bone mass attained in early life is thought to be the most important modifiable determinant of lifelong skeletal health.² Osteoporosis is not restricted to adults; it can occur in children and adolescents. The aim of the present clinical report was to review bone acquisition during infancy, childhood, and adolescence; discuss assessment of bone health, particularly as it applies to children and adolescents; and update pediatricians on strategies to improve bone health in the pediatric age group. Bone

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health needs of pregnant women, lactating mothers, and preterm infants are discussed elsewhere.^{3,4} This clinical report has been endorsed by American Bone Health, a national, community-based organization that provides education programs, tools, and resources to help the public understand bone disease and bone health.

BONE ACQUISITION DURING CHILDHOOD AND ADOLESCENCE

Bone is a living structure comprising a matrix of collagen, hydroxyapatite crystals, and noncollagenous proteins. The matrix becomes mineralized with deposits of calcium and phosphate, which confers strength to the structure. Bone mineral deposition begins during pregnancy, with two-thirds of in utero accrual occurring during the third trimester.⁵ Bone mineral content (BMC) increases 40-fold from birth until adulthood, and peak bone mass is achieved toward the end of the second decade of life, although there may still be some net bone deposition into the third decade.^{6–11} Approximately 40% to 60% of adult bone mass is accrued during the adolescent years, with 25% of peak bone mass acquired during the 2-year period around peak height velocity. After infancy, peak bone mineral accretion rates occur, on average, at 12.5 years for girls and 14.0 years for boys.¹² At age 18 years, approximately 90% of peak bone mass has been accrued.¹³ Childhood and adolescence, therefore, are critical periods for skeletal mineralization. Age of peak bone mass accrual lags behind age of peak height velocity by approximately 6 to 12 months in both boys and girls.¹² This dissociation between linear growth and bone mineral accrual may confer increased vulnerability to bone fragility and may explain, to some degree, the increased rate of forearm fractures in boys 10 through 14 years of age and

in girls 8 through 12 years of age.^{14,15} After peak bone mass is achieved, there is a slow but progressive decline in bone mass until a theoretical fracture threshold is reached. Any condition interfering with optimal peak bone mass accrual can, therefore, increase fracture risk later in life.

The skeleton is an active organ, constantly undergoing remodeling, even after linear growth has been completed. During remodeling, bone formation, mediated via osteoblasts, and bone resorption, mediated by osteoclasts, occur concurrently. Remodeling is regulated by local cytokines as well as by circulating hormones, including parathyroid hormone (PTH), 1,25-dihydroxyvitamin D (1,25-OH₂-D), insulin-like growth factor 1 (IGF-1), and calcitonin. In young children, the rate of cortical bone remodeling is as high as 50% per year. Net bone mass depends on the balance between bone resorption and bone formation. If formation exceeds resorption, as it should during childhood and adolescence, net bone mass increases. If resorption exceeds formation, net bone mass is reduced.

PRIMARY PREVENTION: OPTIMIZING BONE HEALTH IN HEALTHY CHILDREN

Factors affecting bone health are shown in Table 1. Genetic factors account for approximately 70% of the variance in bone mass,¹⁶ although no specific responsible genes have been identified. Male subjects have higher bone mass than female subjects, and black women have higher bone mass than white non-Hispanic women or Asian women. Mexican-American women have bone densities between those of white non-Hispanic and black women. Modifiable determinants of bone mass include nutritional intake of calcium, vitamin D, protein, sodium, and carbonated beverages (ie, soda); exercise and lifestyle;

TABLE 1 Factors Affecting Bone Mass

Nonmodifiable
Genetics
Gender
Ethnicity
Modifiable
Nutrition
Calcium
Vitamin D
Sodium
Protein
Soda
Exercise and lifestyle
Body weight and composition
Hormonal status

maintenance of a healthy body weight, and hormonal status. Nutrition and physical activity are each necessary and function synergistically to improve bone acquisition and maintenance.

CALCIUM

Calcium is necessary for bone accretion, and dietary calcium intake during infancy, childhood, and adolescence affects bone mass acquisition. Approximately 99% of total body calcium is found in the skeleton, and calcium is absorbed by both passive and active transport, the latter mediated by vitamin D. Milk intake during childhood and adolescence is associated with higher BMC and reduced fracture risk in adulthood.¹⁷ The Institute of Medicine (IOM) has published updated dietary reference intakes for calcium and vitamin D, and the American Academy of Pediatrics (AAP) endorses these recommendations for infants, children, and adolescents (Table 2).¹⁸ The recommended dietary allowance (RDA) is the dietary intake that meets the requirements of almost all (97.5%) of the population. Adequate intake is a single value likely to meet the needs of most children and is used for infants younger than 12 months, for whom RDAs have not been established. The upper limit represents the highest average total daily intake likely to pose no risk

of adverse health effects for most people in that age group.

Sources of Calcium

Term Infants and Children

The primary source of nutrition for healthy term infants in the first year of life is human milk or, alternatively, infant formula if human milk is not available. Although the BMC may be higher in formula-fed infants than in breastfed infants in the first year of life, the breastfed infant does not demonstrate any evidence of clinical mineral deficiency, and there is no evidence that the breastfed infant should not be the standard for bone mineral accretion. No data support high mineral intake or supplementation with calcium for healthy breastfed infants.¹⁹ After the first year of life, the major source of dietary calcium is milk and other dairy products, which together account for 70% to 80% of dietary calcium intake. Each 8-oz (240-mL) serving of milk provides approximately 300 mg of calcium, and the calcium content of low-fat or flavored milk is similar to that of whole milk (Table 3).²⁰ However, low-fat chocolate milk contains added sugar and more calories than does low-fat plain milk. One cup of yogurt or 1.5 oz of natural cheese each provides approximately 300 mg of calcium. Other dietary sources of calcium include green leafy vegetables, legumes, nuts, and calcium-fortified breakfast

cereals and fruit juices. Vegetables contributed approximately 7% of the calcium in the food supply between 2000 and 2006.²¹ Bioavailability of calcium from vegetables is generally high but is reduced by binding with oxalates in spinach, collard greens, rhubarb, and beans. Although vegetables are a good source of bioavailable calcium, the quantity of vegetables required to meet daily requirements is substantial, making it difficult to attain dietary calcium requirements with vegetables alone. Certain cereals (eg, whole bran cereals) contain phytates, which also reduce bioavailability.

Preadolescents and Adolescents

The calcium RDA for preadolescents and adolescents aged 9 through 18 years is 1300 mg/d. In the United States, the average dietary calcium intake of adolescent girls is 876 mg/d (67% of the RDA), and less than 15% meet the RDA.²² In 2011, only 14.9% of high school students drank three or more 8-oz servings of milk per day, with only 9.3% of girls doing so.²³ Milk consumption by adolescents has declined at the same time that soda consumption has increased.²⁴ Some adolescent girls avoid milk products because they consider them to be “fattening.” Such myths should be dispelled. For example, one 8-oz serving of skim milk contains no fat and only approximately 80 kcal, approximately the same caloric content

as an apple. In contrast, a can of soda contains 140 kcal. Furthermore, milk provides protein and a number of important nutrients other than calcium, including vitamin D, phosphorus, and magnesium, which are important in bone health. Milk alternatives, such as soy- or almond-based beverages, may have a reduced amount of bioavailable calcium per glass, even when fortified with calcium.²⁵ Further research is needed regarding the mineral levels and bioavailability of these beverages.

Lactose intolerance occurs in children and adolescents and is more common in black, Hispanic, and Asian subjects. Some of these children and adolescents will be able to tolerate small amounts of dairy products other than milk. Others may benefit from lactose-reduced or lactose-free milks and cheeses and/or lactase enzymes.²⁶

Calcium Supplementation

Although a number of studies have demonstrated a positive effect of calcium supplementation on BMC in healthy children and adolescents,^{27,28} a recent meta-analysis of randomized controlled trials examining the effectiveness of calcium supplementation in increasing BMD in healthy children found that there was no effect of calcium supplementation on BMD of the lumbar spine or femoral neck; a small effect was noted on upper-limb BMD and total body BMC equivalent to approximately

TABLE 2 Calcium and Vitamin D Dietary Reference Intakes

Age	Calcium		Vitamin D	
	RDA (mg/d) (Intake That Meets Needs of $\geq 97.5\%$ of Population)	UL (mg/d) ^a	RDA (IU/d) (Intake That Meets Needs of $\geq 97.5\%$ of Population)	UL (IU/d) ^a
Infants				
0–6 mo	200 ^b	1000	400 ^b	1000
6–12 mo	260 ^b	1500	400 ^b	1500
1–3 y	700	2500	600	2500
4–8 y	1000	2500	600	3000
9–13 y	1300	3000	600	4000
14–18 y	1300	3000	600	4000

^a Upper limit (UL) indicates level above which there is risk of adverse events. The UL is not intended as a target intake (no consistent evidence of greater benefit at intake levels above the RDA).

^b Reflects adequate intake reference value rather than RDA. RDAs have not been established for infants.

TABLE 3 Dietary Sources of Calcium

Food	Serving Size	Calories per Portion	Calcium Content (mg)
Dairy foods			
Milk			
Whole milk	8 oz	149	276
Reduced fat milk (2%)	8 oz	122	293
Low-fat milk (1%)	8 oz	102	305
Skim milk (nonfat)	8 oz	83	299
Reduced-fat chocolate milk (2%)	8 oz	190	275
Low-fat chocolate milk (1%)	8 oz	158	290
Yogurt			
Plain yogurt, low-fat	8 oz	143	415
Fruit yogurt, low-fat	8 oz	232	345
Plain yogurt, nonfat	8 oz	127	452
Cheese			
Romano cheese	1.5 oz	165	452
Swiss cheese	1.5 oz	162	336
Pasteurized processed American cheese	2 oz	187	323
Mozzarella cheese, part skim	1.5 oz	128	311
Cheddar cheese	1.5 oz	171	307
Muenster cheese	1.5 oz	156	305
Nondairy foods			
Salmon	3 oz	76	32
Sardines, canned	3 oz	177	325
White beans, cooked	1 cup	307	191
Broccoli, cooked	1 cup	44	72
Broccoli, raw	1 cup	25	42
Collards, cooked	1 cup	49	226
Spinach, cooked	1 cup	41	249
Spinach, raw	1 cup	7	30
Baked beans, canned	1 cup	680	120
Tomatoes, canned	1 cup	71	84
Calcium-fortified food			
Orange juice	8 oz	117	500
Breakfast cereals	1 cup	100–210	250–1000
Tofu, made with calcium	0.5 cup	94	434
Soy milk, calcium fortified ^a	8 oz	104	299

Data source: Dietary Guidelines for Americans, 2010. Available at: www.ndb.usda.gov.

^a Not all soy beverages are fortified to this level.

a 1.7% increase in bone mass.²⁹ The investigators concluded that, from a public health perspective, calcium supplementation of healthy children is unlikely to result in a clinically significant reduction in fracture risk. For most children and adolescents, the emphasis should be on establishing healthy dietary behaviors with a well-balanced diet that includes calcium intake at or near the recommended levels throughout childhood and adolescence. Dietary sources of calcium should be recommended in preference to calcium supplements, not only because of the improved bioavailability of dietary sources of calcium, but also primarily to encourage lifelong healthy dietary habits.

VITAMIN D

Vitamin D (calciferol) is a fat-soluble hormone necessary for calcium absorption and utilization. Without vitamin D, only 10% to 15% of dietary calcium is absorbed.³⁰ Vitamin D includes endogenous conversion of vitamin D₂, ingested animal-derived cholecalciferol (vitamin D₃), and plant-derived ergocalciferol (vitamin D₂). Although there is increasing evidence that vitamin D may also have potential benefits on cardiometabolic risk factors, immunity, and cancer prevention, the focus of the present report is on bone health.

In 2011, the IOM revised the RDAs for vitamin D intake to be higher than previous recommendations (Table 2), and

the AAP endorsed these recommendations.³¹ Vitamin D deficiency results in rickets in young children (peak incidence: 3–18 months of age) and increased fracture risk in older children, adolescents, and adults. Deficiency is particularly common in those living in northern climates, those with dark skin, and those with inadequate exposure to sunlight, but deficiency also occurs in sunny climates.^{32,33} National US data reveal higher rates of vitamin D deficiency in adolescents compared with younger children³⁴ and increasing prevalence from the 1988–1994 to 2001–2004 data collections.³⁵ Cross-sectional studies of vitamin D status in adolescents have found deficiency in 17% to 47% of adolescents,^{32,33,36,37} with increased risk in black and Hispanic teenagers^{33,37,38} and lower vitamin D concentrations in the winter.^{36–38} Children and adolescents who are obese are at increased risk,^{33,39,40} possibly because of sequestration of vitamin D in body fat. Certain medications, such as anticonvulsant, glucocorticoid, antifungal, and antiretroviral medications, increase requirements and predispose subjects to deficiency. Severe vitamin D deficiency is associated with reduced bone mass in adolescents.^{41,42} On the basis of results of a longitudinal prospective study of 6712 physically active girls aged 9 through 15 years, vitamin D intake—not calcium or dairy intake—during childhood is associated with reduced risk of stress fractures.⁴³

Vitamin D₃ is synthesized in the skin from 7-dehydrocholesterol on exposure to sunlight, binds to vitamin D-binding protein, and is transported to the liver where it undergoes hydroxylation to form 25-hydroxyvitamin D (25-OH-D). The half-life of 25-OH-D is 2 to 3 weeks, and serum 25-OH-D is a good indicator of vitamin D stores. Circulating 25-OH-D undergoes a second round of hydroxylation in the kidney to form 1,25-OH₂D, the active form of the hormone. In

contrast to 25-OH-D, 1,25-OH₂-D has a half-life of 4 hours.⁴⁴ Under control of PTH, 1,25-OH₂-D promotes intestinal absorption of calcium and phosphorus, increases renal reabsorption of filtered calcium, and mobilizes calcium from skeletal stores.

Sources of Vitamin D

Sunlight

Exposure to UV B radiation in the range of 290 to 315 nm from sunlight is the major source of vitamin D. Synthesis of vitamin D depends on latitude, skin pigmentation, sunscreen use, and time of day of exposure. Synthesis of vitamin D is minimal during winter months north of 33° latitude in the northern hemisphere and south of 33° latitude in the southern hemisphere. Exposure of arms and legs to 0.5 minimal erythral dose of sunlight for 5 to 15 minutes, 2 to 3 times a week, produces approximately 3000 IU of vitamin D.³¹ Subjects with dark skin require exposure 3 to 5 times longer. Sunscreen with a sun protection factor 8 or higher effectively prevents transmission of UV B radiation through the skin and blocks the synthesis of vitamin D₃. Maximal synthesis occurs between the hours of 10:00 AM and 3:00 PM in the spring, summer, and fall.⁴⁵ Children and adolescents are spending more time indoors and, because of concerns regarding skin cancer later in life, when they do go outside, they often wear sun protection, which limits the skin's ability to synthesize vitamin D. With decreased synthesis of vitamin D from reduced sun exposure, dietary sources of vitamin D become more important.

Dietary Sources

Natural dietary sources of vitamin D are limited but include cod liver oil, fatty fish (eg, salmon, sardines, tuna), and fortified foods. Farm-raised salmon has lower concentrations of vitamin D than does fresh, wild-caught salmon.³¹ Human milk does not provide adequate amounts of vitamin D (approximately

20 IU/L). In the United States and Canada, all infant formula is fortified with vitamin D. Cow milk, infant formula, and fortified fruit juices each contain approximately 100 IU of vitamin D per 8 oz (Table 4).

Recommended Daily Intake and Vitamin D Supplementation

Adequate vitamin D intake for infants younger than 1 year is 400 IU/d. The RDA is 600 IU for children 1 year and older. Because human milk contains inadequate amounts of vitamin D (unless the lactating mother is taking supplements of approximately 6000 IU/d), breastfed and partially breastfed infants should be supplemented with 400 IU of vitamin D per day beginning in the first few days of life and continued until the infant has been weaned and is drinking at least 1 L/d of vitamin D-fortified infant formula or cow milk. Daily supplementation of breastfed infants with 400 IU of vitamin D during the first months of life increases 25-OH-D amounts to normal concentrations.^{46,47} Although the RDA

for children older than 1 year and for adolescents is 600 IU, children who are obese and children on anticonvulsant, glucocorticoid, antifungal, and anti-retroviral medications may require 2 to 4 times the recommended dose of vitamin D to achieve serum 25-OH-D values the same as children without these conditions; at this time, however, definitive recommendations for these children remain unavailable.

Although approximately 98% of cow milk in the United States is fortified with vitamin D, some yogurts, cheeses, juices, and breakfast cereals are also fortified with similar amounts of vitamin D (Table 4) and can generally be recommended in preference to nonfortified foods. For those who are unable to achieve adequate amounts of vitamin D in their diet or who have vitamin D deficiency, vitamin D supplements are available in 2 forms: vitamin D₂ (ergocalciferol), derived from plants, and vitamin D₃ (cholecalciferol), synthesized by mammals. Drisdol (Sanofi-Aventis US,

TABLE 4 Sources of Vitamin D

Food	Serving Size	Vitamin D Content ^a (IU)
Natural sources		
Salmon		
Fresh wild	3.5 oz	600–1000
Fresh farmed	3.5 oz	100–250
Sardines, canned	3.5 oz	300
Mackerel, canned	3.5 oz	250
Tuna, canned	3.5 oz	236
Shitake mushroom		
Fresh	3.5 oz	100
Canned	3.5 oz	1600
Egg, hard-boiled	3.5 oz	20
Vitamin D-fortified foods		
Infant formula	1 cup (8 oz)	100
Milk	1 cup (8 oz)	100
Orange juice ^b	1 cup (8 oz)	100
Yogurts ^b	1 cup (8 oz)	100
Cheeses ^b	3 oz	100
Breakfast cereals ^b	1 serving	40–100
Pharmaceutical sources in the United States		
Vitamin D ₂ (ergocalciferol)	1 capsule	50 000
Drisdol (vitamin D ₂) liquid	1 cc	8000
Supplemental sources		
Multivitamin		400, 500, 1000
Vitamin D ₃		400, 800, 1000, 2000, 5000, 10 000, 50 000

^a The activity of 40 IU of vitamin D is equivalent to 1 µg.

^b Not all brands of orange juice, yogurt, and cheese are fortified with vitamin D.

Bridgewater, NJ) is a vitamin D₂ preparation that contains 8000 IU/mL, and most multivitamins contain 400 IU per tablet. Some calcium preparations also contain vitamin D. In adolescent girls, supplementation of 200 to 400 IU of vitamin D₃ was effective in increasing BMD in a dose-response manner.⁴⁸ The daily upper limits are as follows: infants up to 6 months of age: 1000 IU; infants 6 to 12 months of age: 1500 IU; children 1 through 3 years of age: 2500 IU; children 4 through 8 years of age: 3000 IU; and children and adolescents 9 through 18 years of age: 4000 IU (Table 2).

Assessment of Vitamin D Status

Measurement of serum 25-OH-D concentration reflects both endogenous synthesis and dietary intake of vitamin D and is the optimal method of assessment of vitamin D status.⁴⁵ The 2011 RDAs were selected to ensure that nearly all those who receive the RDA will have a serum 25-OH-D concentration greater than 20 ng/mL. This value was derived on the basis of an assumption of minimal exposure to sunlight and minimal solar vitamin D conversion. The 25-OH-D concentration of 20 ng/mL was also set as a target by the Pediatric Endocrine Society and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition.^{44,49} In contrast, the Endocrine Society has defined vitamin D deficiency as a 25-OH-D concentration <20 ng/mL (50 nmol/L) and insufficiency as a 25-OH-D concentration between 21 and 29 ng/mL (52.3–72.5 nmol/L).⁴⁵ Controversy remains as to whether there are specific health benefits to a higher target, such as 30 ng/mL or higher, for healthy children. In a population of healthy white Danish and Finnish girls, a daily intake of approximately 750 IU of vitamin D was necessary to enable 97.5% of the subjects to achieve a 25-OH-D concentration above 20 ng/mL, in support of the IOM recommendations.⁵⁰

Screening for Vitamin D Deficiency

Evidence is insufficient to recommend universal screening for vitamin D deficiency. The Endocrine Society recommends that “at-risk individuals” should be screened; these include children with obesity, black and Hispanic children, children with malabsorption syndromes, and children on glucocorticoid, anticonvulsant, antifungal, and antiretroviral medications.⁴⁵ There is concern, however, with these recommendations, because they would involve screening, treating, and retesting large numbers of children without good evidence of the cost–benefit in reducing fracture risk (as opposed to improving serum 25-OH-D concentrations) in a healthy population.⁵¹ For example, black youth have lower 25-OH-D concentrations than do white youth, but black subjects also have higher bone mass and reduced fracture risk. The IOM and existing AAP reports do not make recommendations specific to screening. In the absence of evidence supporting the role of screening healthy individuals at risk for vitamin D deficiency in reducing fracture risk and the potential costs involved, the present AAP report advises screening for vitamin D deficiency only in children and adolescents with conditions associated with reduced bone mass and/or recurrent low-impact fractures. More evidence is needed before recommendations can be made regarding screening of healthy black and Hispanic children or children with obesity. The recommended screening is measuring serum 25-OH-D concentration, and it is important to be sure this test is chosen instead of measurement of the 1,25-OH₂-D concentration, which has little, if any, predictive value related to bone health.

Treatment of Vitamin D Deficiency

Both vitamin D₂ and vitamin D₃ increase serum 25-OH-D concentrations. In adults, some^{52,53} but not all⁵⁴ studies

have suggested that vitamin D₃ is more effective in increasing serum 25-OH-D concentrations than is vitamin D₂. In infants and toddlers, 2000 IU of vitamin D₂ daily, 2000 IU of vitamin D₃ daily, and 50 000 IU of vitamin D₂ weekly were equivalent in increasing serum 25-OH-D concentrations.⁵⁵ Infants and toddlers with vitamin D deficiency can be given 50 000 IU of vitamin D₂ or vitamin D₃ weekly for 6 weeks or 2000 IU of vitamin D₂ or vitamin D₃ daily for 6 weeks, followed by a maintenance dose of 400 to 1000 IU/d. Children and adolescents can be treated with vitamin D₂ or vitamin D₃ (50 000 IU, 1 capsule weekly) for 6 to 8 weeks or 2000 IU of vitamin D₂ or vitamin D₃ daily for 6 to 8 weeks to achieve a serum 25-OH-D concentration greater than 20 ng/mL, followed by a maintenance dose of 600 to 1000 IU/d (Table 5).^{18,45} After completion of treatment, repeat serum 25-OH-D concentrations should be obtained. It is not unusual for a second course of treatment to be necessary to achieve adequate concentrations of serum 25-OH-D. There is no strong evidence about whether to treat healthy children who have serum 25-OH-D concentrations between 21 and 29 ng/mL.

SODA CONSUMPTION, PROTEIN, AND OTHER MINERALS

In 2010, 24.3% of US high school students drank at least 1 serving of soda daily.⁵⁶ A recent meta-analysis of 88 studies reported that soda consumption is associated with lower intake of milk and calcium, and larger effect sizes were found with longitudinal and experimental studies compared with cross-sectional studies. The replacement of milk in the diet by soda can prevent adolescents from achieving adequate calcium and vitamin D intake, and because soda consumption has no health benefit, it should be avoided.⁵⁷

Diets low in protein or high in sodium will predispose subjects to reduced

calcium retention.^{58,59} Sodium and calcium share the same transport system in the proximal tubule, and a high-sodium diet promotes increased urinary calcium excretion and should be avoided.

EXERCISE AND LIFESTYLE

Mechanical forces applied to the skeleton (mechanical loading) increase bone formation, and weight-bearing exercise improves bone mineral accrual in children and adolescents.⁶⁰ In healthy children, an exercise program incorporating high-impact, low-frequency exercises such as jumping, skipping, and hopping for 10 minutes 3 times a week increased BMD of the femoral neck in the intervention group compared with control subjects.^{61–63} The greatest effect was observed in children in early puberty. A population-based prospective controlled trial in Sweden demonstrated that a school-based, moderately active, 4-year exercise program increased bone mass and size in children aged 7 through 9 years without increasing fracture risk.⁶⁴ Adolescent female athletes have higher BMD than nonathletes, provided they are menstruating regularly. When female athletes become amenorrheic, the protective effect of exercise on BMD is lost.⁶⁵ Children who are immobilized have rapid declines in bone mass.

Increases in BMD are site specific, depending on the loading patterns of the specific sport. For example, BMD is greater in gymnasts at the hip and spine, in runners at the femoral neck, and in rowers at the lumbar spine; tennis players have higher radial BMD in the

dominant arm than in the nondominant arm. High-impact sports (eg, gymnastics, volleyball, karate) or odd-impact sports (eg, soccer, basketball, racquet sports) are associated with higher BMD and enhanced bone geometry.⁶⁶

For most children and adolescents, walking, jogging, jumping, and dancing activities are better for bone health than are swimming or bicycle riding. Excessive high-impact exercise can, however, increase fracture risk. A prospective longitudinal study of 6831 high school girls found that those who participated in more than 8 hours per week of running, basketball, cheerleading, or gymnastics were twice as likely to sustain a fracture compared with less active girls. The authors suggested that girls who participate in these sports should also include cross-training in lower impact activities.⁶⁷

Lifestyle choices may also confer additional risk for BMD deficits. In adults, smoking, caffeine, and alcohol intake are all associated with reduced BMD,^{68–70} and these behaviors should be avoided in children and adolescents.

BODY WEIGHT

Body weight and composition are important modifiable determinants of bone mass. Mechanical loading during weight-bearing activities stimulates bone formation, and multiple studies in healthy adolescents^{8,71–73} and in those with anorexia nervosa^{74–77} have demonstrated that BMD is directly correlated with BMI. Lean body mass is most strongly associated with BMD,⁷⁸ but increased adiposity can also be associated with

increased fracture risk.⁷⁹ Maintenance of a healthy body weight during childhood and adolescence is therefore recommended to optimize bone health.

HORMONAL STATUS

Several hormones affect bone mass. Estrogen plays an important part in maintaining BMD in women, and estrogen deficiency is associated with increased bone resorption and increased fracture risk. Testosterone, growth hormone, and IGF-1 all promote bone formation, whereas glucocorticoid excess both increases bone resorption and impairs bone formation.

**SECONDARY PREVENTION:
ASSESSMENT OF POPULATIONS AT
RISK FOR INCREASED BONE
FRAGILITY**

**Conditions Associated With
Reduced Bone Mass in Children
and Adolescents**

Conditions associated with reduced bone mass and increased fracture risk in children and adolescents are listed in Table 6. Osteogenesis imperfecta, idiopathic juvenile osteoporosis, and Turner syndrome are rare conditions with increased bone fragility, best managed by pediatric endocrinologists, geneticists, and specialists in pediatric bone health. Children with chronic illnesses are, however, frequently managed by general pediatricians. Cystic fibrosis, systemic lupus erythematosus, juvenile idiopathic arthritis, inflammatory bowel disease, celiac disease, chronic renal failure, childhood cancers, and cerebral palsy

TABLE 5 Treatment of Vitamin D Deficiency

Age	Preparation and Dose ^a	
Infants, 0–12 mo	Vitamin D ₂ or D ₃ 50 000 IU weekly for 6 wk Followed by a maintenance dose of 400–1000 IU daily	or Vitamin D ₂ or D ₃ 2000 IU daily for 6 wk
Children and adolescents, 1–18 y	Vitamin D ₂ or D ₃ 50 000 IU weekly for 6–8 wk Followed by a maintenance dose of 600–1000 IU daily	or Vitamin D ₂ or D ₃ 2000 IU daily for 6–8 wk

Vitamin D₂, ergocalciferol; vitamin D₃, cholecalciferol.

^a Vitamin D₃ may be more potent than vitamin D₂.

can all be associated with reduced bone mass.^{78,80–84} Risk factors include malnutrition, increased metabolic requirements, intestinal malabsorption, low body weight, chronic inflammation with increased cytokine production, hypogonadism, immobilization, and the effects of prolonged glucocorticoid therapy. Children with cerebral palsy are at particular risk. One study found that 77% of children with cerebral palsy had a femoral neck BMD z score less than –2.0, and 26% of children older than 10 years had sustained a fracture.⁸⁴

Eating disorders are prevalent in adolescents.⁸⁵ Anorexia nervosa is associated with reduced BMD and increased fracture risk,^{74–76,86–89} and the reduction in bone mass occurs after a relatively short duration of illness.^{74,90} Etiologic

factors include poor nutrition, low body weight, estrogen deficiency, and hypercortisolism. The degree of reduction of BMD is directly related to the degree of malnutrition, and in girls, is related to the duration of amenorrhea. Low BMD is also found in boys with anorexia nervosa and is associated with low testosterone concentrations.⁹¹ Patients with partial eating disorders or those with bulimia nervosa may also have reduced bone mass, especially if they are or have been of low weight.^{89,92,93} The “female athlete triad” refers to 3 interrelated conditions seen in female athletes: low energy availability, menstrual dysfunction, and reduced BMD.⁹⁴ Low energy availability refers to inadequate energy intake for the level of physical activity. The energy deficit may be unintentional secondary to a lack of knowledge regarding the increased energy requirements of athletes or it may be intentional and associated with an underlying eating disorder. There is suppression of the hypothalamic-pituitary-ovarian axis, resulting in amenorrhea, a low estrogen state, reduced bone mass, and increased fracture risk.

Endocrine conditions associated with glucocorticoid or PTH excess, hypogonadism, hyperthyroidism, or deficiency of growth hormone or IGF-1 are all associated with low bone mass (Table 6). Certain medications, including anticonvulsants and chemotherapeutic agents, prolonged use of proton pump inhibitors, and selective serotonin reuptake inhibitors, can also have a negative effect on bone mass. Depot medroxyprogesterone acetate (DMPA) is a very effective long-acting contraceptive that has been credited, to some degree, for the reduction in adolescent pregnancy rates in the United States over the past decade. Prolonged use of DMPA in adolescent girls is associated with hypothalamic suppression and reduced bone mass, however.⁹⁵ In 2004, the US Food and

Drug Administration issued a black box warning to inform practitioners about the negative effects of DMPA on bone mass. Discontinuation of DMPA is associated with rapid improvements in bone mass, although it is not known how much of potential maximum peak bone mass is recovered.⁹⁶ For most adolescents, the risk of fracture while taking DMPA is low, and the benefit of taking the medication outweighs the risks. The Society for Adolescent Health and Medicine recommends continuing to prescribe DMPA to adolescent girls needing contraception but recommends explanation of the risks and benefits.⁹⁷ The American College of Obstetrics and Gynecology further states that concerns about the effect of DMPA on BMD should neither prevent practitioners from prescribing it nor limit its use to 2 consecutive years.⁹⁸ In adolescent girls, low-dose oral contraceptives containing less than 30 µg of ethinyl estradiol may interfere with peak bone mass acquisition compared with oral contraceptives containing ≥30 µg of ethinyl estradiol.^{99,100} Despite a possible reduction in BMD in oral contraceptive users, a recent Cochrane review of observational studies found no association between oral contraceptive use and increased fracture risk.¹⁰¹

Assessment of Bone Health

The ideal method of assessment of clinically relevant bone health is determination of fracture risk on the basis of longitudinal data. However, there is a paucity of longitudinal studies examining factors affecting bone health in children on the basis of incidence of fractures. Fracture risk depends not only on skeletal fragility but also on age, body weight, history of fractures, and the force of an injury. Skeletal fragility, in turn, is dependent on a number of factors in addition to bone mass, including bone size, geometry, microarchitecture, and bending strength. For example, bending strength depends on the radius of a bone,

TABLE 6 Conditions Associated With Reduced Bone Mass in Children and Adolescents

Genetic conditions
Osteogenesis imperfecta
Idiopathic juvenile osteoporosis
Turner syndrome
Chronic illness
Cystic fibrosis
Connective tissue disorders (lupus, juvenile idiopathic arthritis, juvenile dermatomyositis)
Inflammatory bowel disease, celiac disease
Chronic renal failure
Childhood cancer
Cerebral palsy
Chronic immobilization
Eating disorders, including anorexia nervosa, bulimia nervosa, eating disorders not otherwise specified, and the female athlete triad
Endocrine conditions
Cushing syndrome
Hypogonadism
Hyperthyroidism
Hyperparathyroidism
Growth hormone deficiency
Diabetes mellitus
Medications
Glucocorticoids
Anticonvulsants
Chemotherapy
Leuprolide acetate
Proton pump inhibitors
Selective serotonin reuptake inhibitors
DMPA

and a large bone will be more resistant to fracture than a smaller bone, even when both bones have the same BMC or BMD. Bone mass, which accounts for approximately 70% of bone strength, can be used as a surrogate measure of bone health, recognizing that a low bone mass in children does not necessarily translate to increased fracture risk.

Dual-energy x-ray absorptiometry (DXA) is the preferred method of assessment of bone mass because of its availability, speed, precision, and low dose of radiation (5–6 mSv for the lumbar spine, hip, and whole body, which is less than the radiation exposure of a transcontinental flight and one-tenth that of a standard chest radiograph).¹⁰² DXA measures BMC and calculates areal BMD by dividing BMC by the area of the region scanned. DXA machines are widely available, and robust pediatric reference databases for children older than 5 years are included with the software of the major DXA manufacturers.^{103–106} In pediatric patients, the preferred sites of measurement are the lumbar spine and whole body.¹⁰⁷ In children, the hip is less reliable because of variability in positioning and difficulties identifying bony landmarks. Scanning time of the hip or spine is less than 1 minute; for the whole body, it is approximately 5 minutes. In adults, each SD reduction in BMD below the young adult mean doubles the fracture risk. Osteoporosis is operationally defined as a BMD 2.5 or more SDs below the young adult mean (a T score less than –2.5), and osteopenia is defined as a BMD ≥ 1 SD below the young adult mean (a T score of less than –1.0). However, caution should be used in interpreting DXA results in children. First, because children have not yet achieved peak bone mass, z scores (the number of SDs below the age-matched mean) should be used instead of T scores. Second, DXA measures 2-dimensional areal BMD (expressed as grams per square centimeter), as

opposed to 3-dimensional volumetric BMD (expressed in grams per cubic centimeter), and areal BMD underestimates true volumetric BMD in subjects with smaller bones. Third, many children with chronic illness have growth retardation and delayed puberty. Therefore, a correction should be made for height or height age, and a number of mathematical corrections have been proposed.^{108–110}

The International Society for Clinical Densitometry recommends that the term “osteopenia” no longer be used in pediatric DXA reports and that the diagnosis of osteoporosis not be made on the basis of DXA results alone.¹⁰⁷ In the pediatric age group, the diagnosis of osteoporosis requires both a low BMD or BMC (defined as a z score less than –2) and a clinically significant fracture (defined as a long-bone fracture of the lower extremity, a vertebral compression fracture, or 2 or more long-bone fractures of the upper extremity).^{107,111} Longitudinal studies in children and adolescents have demonstrated a high degree of tracking over a period of 3 years.¹¹² In other words, children with low bone density continue to have low bone density over time. In contrast to adults, in pediatrics, there is no specific BMD z score below which fractures are more likely to occur, but there is a growing body of literature demonstrating an association between low bone mass measured by using DXA and fracture risk in children.^{113–115}

Limited evidence is available to guide pediatricians regarding when to order a DXA. In general, a DXA should be performed to identify children and adolescents at risk for skeletal fragility fractures and to guide treatment decisions. The AAP’s “Clinical Report—Bone Densitometry in Children and Adolescents” recommends ordering a DXA for children and adolescents with clinically significant fractures (defined earlier) sustained after minimal trauma

(defined as falling from standing height or less) and in those with medical conditions associated with increased fracture risk.¹¹⁶ Evidence is insufficient to support obtaining a DXA in children and adolescents taking medications that can adversely affect bone or in healthy children with recurrent traumatic fractures of the fingers or toes. DXA scans are usually repeated after 1 year and should not be repeated at an interval of less than 6 months.

Quantitative computed tomography measures true volumetric BMD, but the radiation exposure dose is high (30–7000 mSv). Newer modalities, such as peripheral quantitative computed tomography, can measure volumetric BMD of the appendicular skeleton with much lower radiation doses but are not widely available for clinical use. Quantitative ultrasonography is a noninvasive method of assessing bone health by measuring speed of an ultrasound wave as it is propagated along the surface of bone. This method is difficult to interpret because of a lack of pediatric reference data, however, and poor precision in the pediatric population.

TERTIARY PREVENTION: SPECIFIC TREATMENTS TO INCREASE BONE MASS IN POPULATIONS AT INCREASED RISK OF FRACTURE

In most chronic diseases associated with low BMD, treatment of the underlying condition helps improve bone mass, and specific interventions will depend on the underlying condition.

Calcium Supplementation

Depending on the medical condition, for those children and adolescents who are unable to consume enough calcium from dietary sources, including fortified foods, calcium supplementation can be prescribed. The most common forms of supplemental calcium are calcium carbonate (40% elemental calcium) and calcium citrate (21% elemental calcium).

Calcium carbonate should be taken with meals to promote absorption, but calcium citrate does not require gastric acid for absorption and can be taken on an empty stomach.¹¹⁷ Calcium supplements are available in liquid, tablet, and chewable preparations.

Treatment of Vitamin D Deficiency

Screening for vitamin D deficiency by obtaining a serum 25-OH-D concentration is recommended in patients at increased risk of bone fragility and in those with recurrent low-impact fractures. Although a serum 25-OH-D concentration of 20 ng/mL is considered normal for healthy children and adolescents, some experts aim for achievement of a serum 25-OH-D concentration above 30 ng/mL in populations at increased risk of fracture, given the potential benefits and unlikely risk of toxicity of doses required to achieve this concentration (the upper limit for a child older than 9 years is 4000 IU/d).¹¹⁸ Pediatric treatment regimens for vitamin D deficiency are outlined in Table 5.

Bisphosphonates

Bisphosphonates inhibit osteoclast-mediated bone resorption and have been used to increase BMD and reduce fracture risk in children with osteogenesis imperfecta,^{119–121} cerebral palsy,¹²² and connective tissue disorders^{123,124} and children treated with corticosteroids.^{123,125–127} Pilot studies have also been conducted in adolescents with anorexia nervosa.¹²⁸ In osteogenesis imperfecta, an open-label study examining the use of cyclic administration of intravenous pamidronate reported reduced pain and fractures associated with dramatic increases in BMD.¹¹⁹ A recent multicenter, randomized controlled trial found increases in lumbar spine BMD (51% vs 12% in control subjects) with oral alendronate but no significant change in fracture incidence.¹²¹ Use of bisphosphonates in children remains controversial because

of the potential adverse effects of these agents and their long half-lives. Bisphosphonates are incorporated into bone and may be slowly released from the bone even after the medication has been discontinued. Because of the paucity of studies on efficacy and long-term safety, at this time these agents should not be used to treat asymptomatic reduction in bone mass in children, and their use should be restricted to osteogenesis imperfecta and other select conditions with recurrent fractures, severe pain, or vertebral collapse.^{129,130}

Oral Contraceptives

Adolescent girls with anorexia nervosa or the female athlete triad are frequently prescribed oral contraceptives to improve bone mass, even with no evidence of their efficacy.¹³¹ Prospective cohort studies and randomized controlled trials have both shown that oral contraceptives do not increase bone mass in subjects with anorexia nervosa or in female athletes.^{75,132–135} Because of this lack of demonstrated efficacy, their use is not recommended to increase bone mass. In girls with anorexia nervosa, oral contraceptives will induce monthly menstruation, which may be incorrectly interpreted as an indication of adequate weight restoration.

THE ROLE OF THE PEDIATRICIAN

1. Ask about dairy intake, nondairy sources of calcium and vitamin D, use of calcium and/or vitamin D supplements, soda consumption, and type and amount of exercise at health maintenance visits. Suggested ages to ask these questions are 3 years, 9 years, and during the annual adolescent health maintenance visits.
2. Encourage increased dietary intake of calcium- and vitamin D-containing foods and beverages. Dairy products constitute the major source of dietary calcium, but calcium-fortified

drinks and cereals are available. Low-fat dairy products, including nonfat milk and low-fat yogurts, are good sources of calcium. Children 4 through 8 years of age require 2 to 3 servings of dairy products or equivalent per day. Adolescents require 4 servings per day (Table 3). Suggested targeted questions include: “What kind of milk or dairy products do you consume?” “How many servings do you consume a day?” (One serving is an 8-oz glass of milk, an 8-oz yogurt, or 1.5 oz of natural cheese.) “In addition to dairy, what calcium-fortified foods do you buy or have you thought about buying?” Current data do not support routine calcium supplementation for healthy children and adolescents. The RDA of vitamin D for children 1 year and older is 600 IU. Children who are obese and children on anticonvulsant, glucocorticoid, antifungal, or retroviral medications may require higher doses, but specific end points and targets remain poorly defined.

3. Encourage weight-bearing activities. Walking, jumping, skipping, running, and dancing activities are preferable to swimming or cycling to optimize bone health.
4. Routine screening of healthy children and adolescents for vitamin D deficiency is not recommended. Those with conditions associated with reduced bone mass (Table 6) or recurrent low-impact fractures should have a serum 25-OH-D concentration measured. Those who have vitamin D deficiency should be treated and have 25-OH-D concentrations measured after completion of treatment.
5. Consider a DXA in medical conditions associated with reduced bone mass and increased bone fragility and in children and adolescents with clinically significant fractures sustained after minimal trauma. In

children, z scores should be used instead of T scores. In those with growth or maturational delay, corrections should be made for height or height age.

6. In adolescent female subjects, discourage preoccupation with extreme thinness. A DXA should be considered in an adolescent athlete who has been amenorrheic for more than 6 months. Athletes, parents, and coaches should be educated about the female athlete triad. There is no evidence to support prescribing oral contraceptives to increase bone mass in those with anorexia nervosa or the female athlete triad.
7. Until more studies demonstrating safety and efficacy in other popula-

tions have been conducted, use of bisphosphonates in children and adolescents should be restricted to osteogenesis imperfecta and conditions associated with recurrent fractures, severe pain, or vertebral collapse.

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Out-of-Home Placement for Children and Adolescents With Disabilities

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- *Clinical Report*

CLINICAL REPORT

Out-of-Home Placement for Children and Adolescents With Disabilities

abstract

FREE

The vast majority of children and youth with chronic and complex health conditions who also have intellectual and developmental disabilities are cared for in their homes. Social, legal, policy, and medical changes through the years have allowed for an increase in needed support within the community. However, there continues to be a relatively small group of children who live in various types of congregate care settings. This clinical report describes these settings and the care and services that are provided in them. The report also discusses reasons families choose out-of-home placement for their children, barriers to placement, and potential effects of this decision on family members. We examine the pediatrician's role in caring for children with severe intellectual and developmental disabilities and complex medical problems in the context of responding to parental inquiries about out-of-home placement and understanding factors affecting these types of decisions. Common medical problems and care issues for children residing outside the family home are reviewed. Variations in state and federal regulations, challenges in understanding local systems, and access to services are also discussed. *Pediatrics* 2014;134:836–846

INTRODUCTION

Most children and adolescents with developmental disabilities and chronic health conditions live and thrive at home with their families. However, some of them reside outside their family homes. They usually live in congregate care settings in which 4 or more people receive care for a variety of medical, psychiatric, behavioral, and developmental issues. In the past 35 years, the number of children and adolescents living in residential settings has decreased significantly. In 1977, 36% of residents in state facilities were between 0 and 21 years of age. This total does not include children and youth in residential facilities operated by other entities, such as private corporations and religious orders. There has been a significant decrease in the number of residents living in congregate care settings since that time. However, in 2010, 4% of those living in congregate care were between 0 and 21 years of age; approximately one-third of these subjects ($n = 7926$) were younger than 14 years of age.¹ The shift from people with disabilities living in care centers to community living was accelerated by the Olmstead Act of 1999 (http://www.ada.gov/olmstead/olmstead_about.htm), which stated that unjustified segregation of persons with disabilities violates Title II

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KEY WORDS

children and youth with special health care needs, intellectual and developmental disabilities, out-of-home placement, pediatric skilled nursing facilities

ABBREVIATIONS

AAP—American Academy of Pediatrics
IDD—intellectual and developmental disability
SNF—skilled nursing facility
SSI—Supplemental Security Income

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of the Americans with Disabilities Act. Furthermore, the Olmstead Act mandated that persons with disabilities be provided appropriate and reasonable accommodations for community-based services. Within that context, 1 goal of the Healthy People 2010 program was to “reduce to zero the number of children aged 17 and younger living in congregate care facilities.” The revised goal of Healthy People 2020 is more realistic, aiming to “reduce the number of children and youth aged 21 years and under with disabilities living in congregate care residences” by 10% or from nearly 29 000 children in 2009 to 26 000 children in the next decade.² In 2000, the Centers for Medicare & Medicaid Services reported that there were 4886 children with special health care needs in the United States residing in skilled nursing facilities (SNFs), of whom 1222 had intellectual and developmental disabilities (IDDs).³ Intellectual disability refers to a group of conditions in which there is limited cognitive capacity, significantly reduced adaptive skills, and onset before 18 years of age. Developmental disability is a severe and chronic disability that may affect cognitive and/or physical functioning and has an onset before 22 years of age.⁴ It has been postulated that placement of children and youth (referring to adolescents) with IDDs into SNFs occurs when families are not able to obtain adequate community-based care and support. However, the reasons for placement of children in various types of residential facilities are complex and multifaceted.⁵

In 2005, the Council on Children With Disabilities of the American Academy of Pediatrics (AAP) endorsed the goals of Healthy People 2010, supporting the importance of permanency planning as a means to care for children with special health care needs in the family home.⁶ In response to a published editorial contesting the notion that no

children should be placed in congregate settings,⁷ the Council on Children With Disabilities responded by indicating that, although the AAP endorsed Healthy People 2010, the council did not endorse the specific goal of eliminating congregate care. The council called on the AAP to develop a policy regarding the role of congregate care for children with special health care needs.⁸

The goal of the present report was to review the subject of pediatric congregate care, including the characteristics of children and youth who may be admitted to congregate care centers, definitions of residential placement options, typical reasons for placement, and suggestions for pediatricians who work with children and youth whose families may consider out-of-home placement. This report focused on young people who generally are nonverbal, nonambulatory, and dependent for most or all activities of daily living. Most of these young people have severe to profound intellectual disability, and some have no ability to interact with their environment. Some of the children and adolescents who reside in these settings for respite services or postoperative or rehabilitation care may have less severe presentations or may present with complex and chronic medical conditions, making them totally dependent on others for daily care.

CHILDREN AND YOUTH WITH IDD AND/OR SPECIAL HEALTH CARE NEEDS

Much has been written and acknowledged about the benefits of providing home- and community-based supports for children, adolescents, and adults with a wide range of disabilities and special health care needs.^{9,10} As a result, changes in public and professional awareness, values, policies, funding sources, and programmatic supports have occurred. With these changes, the

vast majority of children and adolescents who require assistance with all or most daily living skills and ongoing skilled nursing care live with their parents.^{1,11} However, children and youth with significant disabilities and special health care needs may have multisystem medical problems that often worsen over time. Children may require care for neurologic, pulmonary, orthopedic, gastrointestinal, endocrine, metabolic, and other medical problems.¹² Although there are home health care agencies and other community-based supports for families, there is substantial variability of resources depending on jurisdiction, funding, diagnosis, and other factors. In addition, not all families have the housing resources or personal capacity to care for children with special needs.

In 2010, approximately one-third of children, adolescents, and adults with IDDs nationwide were on waiting lists for a variety of community-based services and supports.¹¹ At any time, there are more families waiting for services for their children who have technological needs than there are persons available to provide these services, and the necessary funding is not consistent or guaranteed, leaving families to care for their children without professional support. Some children currently residing at home receive more technically demanding care than is possible in many SNFs, including ventilation and intravenous nutrition, placing substantial responsibilities and stresses on families and home life.¹³ The decision to provide this type of care at home may be a choice or a necessity, given some of the financial, resource, and policy constraints.

TYPE OF RESIDENTIAL FACILITIES

There is no consistent definition for the different types of congregate care facilities. The definitions vary state by state, and the term “nursing home”

does not have a formal and generally accepted definition. Nursing homes vary in types of services provided, with “skilled” generally being used to indicate a higher level of nursing care. However, this distinction is not universal, and statistics provided do not clearly make that differentiation. SNFs and intermediate care facilities are places where people live; therefore, these subjects are usually referred to as “residents” rather than patients. Although residents may leave, such as for a visit to their family home, there usually is not an anticipation of a “discharge date.” This type of arrangement differentiates these facilities from transitional settings, residential schools, respite centers, rehabilitation hospitals, and other settings where children may stay for specified periods of time while receiving care related to their disabilities or their medical needs.

SNFs

SNFs, commonly referred to as nursing homes, care for individuals who require 24-hour skilled nursing procedures on a daily basis, regardless of specific diagnosis or etiology, for their medical problems. Pediatric SNFs care for children, youth, and some adults with special health care needs, most of whom also have IDD. Some facilities require residents to have severe to profound intellectual disability for admission. Services provided include ongoing nonoral feeding (eg, gastrostomy or jejunostomy tube feedings), medication administration, suctioning, and skilled assessments. Not every SNF provides the full gamut of technically advanced nursing care, such as tracheostomy care, mechanical ventilator support, intravenous fluid or nutrition, or dialysis. The medical complexity of children admitted to SNFs has increased over the years. In many SNFs, direct patient care is primarily provided by certified nursing assistants

under the direction of registered, licensed practical, or vocational nurses. Physicians make regular rounds, the frequency of which varies between states and even between facilities within the same state; physicians generally are not present on a daily basis. Many facilities also provide short-term respite care, either on a planned or an emergency basis.

The provision of physical, occupational, speech, and behavioral therapies is variable. Specific standards for environmental conditions, staffing levels, and physician certification for facilities caring for children do not exist at a federal level, although standards do exist for SNFs in general. In some states, children can only be admitted to pediatric facilities; in others, they may be admitted to general facilities with or without specific waivers.

Intermediate Care Facilities

Intermediate care facilities are residential facilities that provide daily care for subjects who require care and supervision but who do not require 24-hour-per-day skilled nursing. These services include assistance with activities of daily living, such as feeding, incontinence care, dressing and bathing, medication administration, and safety supervision. They usually do not provide parenteral medication or nonoral feeding.

Acute Care or Specialty Hospitals Providing Long-term Care

Provision of long-term care in this type of setting is a relatively new concept. A physician provides daily assessment and care for patients who require a hospital level of treatment on a long-term basis. This care may include mechanical ventilator management with frequent adjustments, frequent modifications to daily medication regimens, parenteral fluids, and medications, dialysis, complex wound care, and other

medically complex interventions to patients who are not expected to improve in the short-term.

Transitional Facilities

Transitional services are sometimes located within hospital settings and SNFs, although these settings may also be freestanding and located within residential buildings. They primarily provide a transition for patients with skilled care needs who are being discharged from the hospital before returning home. For example, care may be provided to a child with a new tracheostomy while training the family in its use and developing the plan for home care. These facilities also may provide care for children and adolescents with multiple medical needs on a respite or temporary basis or after a change in medical condition, such as postoperative orthopedic surgery care. There is not a consistent definition or licensing for transitional facilities. Although, implicitly, patients are cared for in these settings for relatively short periods of time, the length of placement may vary.

Rehabilitation Hospitals

Rehabilitation hospitals are not congregate care facilities; they provide short-term hospital care with nursing, medication management, and intense rehabilitative therapies. Some SNFs for adults use the term “rehabilitation center,” and some skilled care facilities for adults provide what is termed “subacute rehabilitation,” which implies treatment intended to improve function but at a level less intense than that provided in a rehabilitation hospital. It is unusual for this type of facility to be available for children.

Residential Schools

Some children and adolescents are cared for in residential schools that provide expertise and educational curricula for individuals with specific

health conditions or disabilities. Most of these settings are for children and youth with long-term behavioral or psychiatric problems, although some exclusively serve children with physical or developmental disabilities. The level of nursing and medical care provided within these programs varies. These settings do not provide the same level of care provided in SNFs. The children usually return to their family home during school vacations. These schools may be private or public programs.

Medical Group Homes

In some states, medical group homes have replaced other forms of technologically advanced residential facilities. These homes have providers who typically care for relatively small numbers of patients in adapted single-family homes within residential neighborhoods. Medical group homes may provide nursing care at the level of the SNF.

All of these types of facilities must follow state and/or federal regulations. Skilled care facilities must comply with federal regulations.¹⁴ However, regulations for level of care, environmental safety, staff ratios, and types of residents served, as well as payment sources, vary state by state.¹⁵ Admission is regulated and cannot occur simply by parental or physician request. Specific admission criteria and processes for admission vary by state. In general, individuals younger than 22 years are not able to be placed in adult SNFs, and adults are not admitted to pediatric SNFs. However, there are situations in which subjects obtain waivers to allow for exceptions to these policies. Many states also now allow children to be present in adult SNFs, using “intergenerational models.”

TRANSITIONS TO ADULthood IN CONGREGATE CARE SETTINGS

As young people with significant IDD and special health care needs reach

adulthood, many remain in pediatric facilities because of insufficient community resources to address issues specific to their disabilities and health problems, including insufficient expertise of medical and nursing staff in caring for adults with IDDs in SNFs. In addition, there may be regulations prohibiting the placement of subjects with IDDs in SNFs for adults who are medically fragile but without these types of disabilities. This lack of adequate care options often creates extremely difficult situations for young adults with profound IDDs who have been in residential placement since early childhood and are now over age for the licensed facility where they have always received care. Although some patients remain in the pediatric SNF, the medical and nursing staff may not have experience in the recognition and management of adult medical conditions (e.g., ischemic heart disease). In addition, as adults with IDDs age, many develop special health care needs that may not be adequately met in nonskilled care facilities or at home with aging parents.

CHARACTERISTICS OF CHILDREN WHO LIVE OUTSIDE THE FAMILY HOME

Decades ago, most children referred to residential placement had intellectual or developmental disabilities; some did not have significant medical problems.^{1,2} Certain medical interventions, such as use of feeding tubes and positive-pressure ventilation, were not commonly used in long-term care facilities, with the exception of respiratory care for children with polio. Many families also were encouraged to place their infants with Down syndrome into institutional settings. With the dramatic changes in living situations and community supports for subjects with disabilities over the past 40 years, it would be extremely

difficult to place an infant with Down syndrome who did not have associated chronic complex conditions into an institutional setting today. Home care waivers that allow Medicaid funding for long-term nursing care provided at home, including for families who might not otherwise be financially eligible for Medicaid (e.g., Katie Beckett waivers), began at approximately the same time. The idea, and then the expectation, that long-term sophisticated medical, rehabilitative, and technological care would be provided for children with complicated disabilities co-occurred with support for home care, mandatory eligibility for special education, and the recognition that families of children with developmental disabilities thrived when family members remained together.

The Developmental Disabilities Assistance Bill of Rights Act, section 102,¹⁶ defines developmental disability as a severe, chronic disability that is the result of mental and/or physical impairments, occurs before 22 years of age, is chronic in nature, and results in significant limitations in at least 3 major areas of functioning. Children from birth through age 9 years do not require 3 or more major areas of limitation in the presence of significant developmental delays or specific congenital or acquired conditions, if there is a high likelihood of meeting all criteria later in life if their needs are not addressed. These limitations result in the need for a number of different services and supports for children, youth, and adults.¹⁷ Importantly, most people with developmental disabilities do not have medically complex conditions or chronic illness. There is variability in how states define disability for different types of services, as well as how services are provided to children. Medical diagnoses pertaining to disability generally do not

correspond to educational definitions of disability.¹⁸ Children and adolescents who are medically fragile and/or technology dependent are supported by government, educational, and fiscal programs that do not apply to adults, leading to a significant step-down in services and available supports when reaching adulthood.

Many children and youth who receive skilled care have problems that were acquired or are later-presenting medical conditions, such as acquired brain injury, spinal cord injuries, leukodystrophies, neuromuscular conditions, or catastrophic complications of other illnesses. Although many young individuals in skilled care facilities have severe to profound IDD and complicated medical conditions regardless of etiology, there are some children who require significant medical and technological support in the context of normal or more mildly affected cognitive skills: for example, those with neuromuscular disorders who require assisted ventilation or children and adolescents with long-term need for parenteral nutrition. Their needs for social support, education, recreation, and future planning are different from those of children with severe to profound intellectual disability. The needs of children and adolescents with life-limiting disorders (eg, leukodystrophies) or children whose parents have decided against life-prolonging treatment are also different from those of children with profound disabilities who are expected to live into adulthood.

DIFFERENCES BETWEEN HOME CARE AND RESIDENTIAL CARE

Children and adolescents in congregate care settings are cared for differently than when they are at home. The most obvious difference is that they do not usually have daily contact with parents and siblings, and their care is provided

by different people throughout the day. Families visit their children at variable frequency. Unfortunately, some children have little contact with their families. There also are greater risks of infectious diseases when individuals are in congregate care settings, despite requirements for universal precautions and immunizations.

The care of children and youth in residential settings is driven by physician orders and nursing protocols and may be more regimented than home care (eg, timing of feeding, bathing, and medication administration). Licensed personnel are required to report specific changes and to follow medical orders and facility protocols, whereas parents are free to use their own judgment. Nursing homes may have contractual or regulatory limits on what pharmacies or suppliers they can use; these restrictions may limit access to certain medications, formulas, and types of equipment. In some cases, particularly when there are concerns about the care a family is providing, the protocol-driven nature of congregate care may benefit the child. For example, Henderson et al¹⁹ found that children in residential care who received nonoral feedings demonstrated improved growth compared with children in home care, likely reflective of adherence to specific orders in residential facilities.

Children in residential care retain their rights to a free appropriate public education in the least restrictive setting, and some continue to participate in public schools. Therapy, educational, and recreational services frequently are provided within the facility. Children and adolescents in the community may have providers come into their home, or they may go out to different appointments. There may be fewer environmental barriers in a residential setting, access to multiple caregivers and equipment for lift-

ing, and protocols for care. However, although children and youth in SNFs might have access to technically easier care, round-the-clock caregivers, and an accessible environment that may facilitate recreation and community access, they have extremely limited interaction with typically developing peers. This limitation may be viewed as negative, neutral, or positive, depending on the particular family and child.

REASONS FOR PLACEMENT AND DECISION-MAKING

There have been a number of reports about the reasons for placement of a child, adolescent, or adult family member into a residential setting as well as the effects of that decision on other family members. Factors that affect placement decisions include issues related to the child or youth, family and parental attitudes, cultural practices, influence of the social environment, and the availability (or lack) of external assistance. Some individuals require more care than can be provided in most homes by most families,⁷ although it is clear that some families are able to do more than others for a variety of reasons. Families may not be able to adequately care for their child alone in the context of insufficient community resources, such as a large youth with a high spinal cord injury who is ventilator dependent and requires 2 people to turn him. In other situations, families lack the capability to organize, supervise, and manage a home care staff and may not be able to learn the assessment and technical skills to provide safe care. These decisions are difficult for families, and pediatricians may also be challenged when they believe that a loving family might not be the best provider of care for their own child. Llewellyn et al²⁰ found that parents, as a group, reported their desire to care for their child at home. Despite this

finding, decisions to place a child into a congregate care setting often were made for reasons that the parents considered to be important for the “survival” of the family as a whole.

Perceptions of social challenges also have been found to affect decisions for out-of-home placement in certain situations. In 1 study, parents who expect that their child with disabilities might be stigmatized in the community were found to be more apt to place their child in a residential setting.⁵ Similarly, Hanneman and Blacher²¹ found that the more “normative” the child’s appearance, the less likely families considered residential placement. Conversely, in this report, mothers of higher socioeconomic status and those with more children were more likely to consider out-of-home placement. Stress on the caregiver affected the consideration of placement as well as whether placement actually occurred. Interestingly, support resources and quality of life did not influence placement in this particular study. However, others have found that lack of adequate community-based disability or family support services to meet their particular needs was associated with out-of-home placement.²²

The importance of the well-being of families with children with disabilities has been explored by a number of researchers.^{23,24} Families have been found to make decisions regarding placement that are in the interest of maintaining the highest level of functioning of all family members.²⁵ However, not all families balance the demands of caring for their child with a disability similarly, as the context of other family needs may differ.²⁶ Hostyn and Maes¹⁰ evaluated families who placed their children in residential settings and divided them into 4 groups. Some families, whose children had multiple disabilities, health problems, and complex needs, tended to choose

placement so that the child could lead a comfortable life, with intensive medical and therapeutic supports. These families were also often noted to have difficulty balancing care for the child with disabilities with their other family and work demands. The authors also described families who had children with a developmental disability coupled with significant behavioral problems. These families tended to choose placement because they were not able to handle a child’s behavior, felt guilty and powerless, and were often socially isolated. Some of them also had concerns about the effects of negative behaviors on their other children. In general, children with these characteristics are not appropriate candidates for SNFs because they do not require skilled nursing procedures and they may be independent in activities of daily living. A third type of family was one in which 1 or both parents had physical or mental health problems or an intellectual disability. They also tended to have fewer educational opportunities, social supports, and available resources and were more likely to be unemployed or underemployed. The decision for out-of-home placement in these cases was found to be based on the parents’ feelings of inadequacy to care for their child. A fourth type of family was one in which the primary caregivers were divorced. Although both parents may be much involved in their child’s life, they perceived little support from others. In all groups, parental concern for the well-being of family members other than the child with disabilities was noted, and parents also voiced the belief that residential placement would better support their child with disabilities.

Parents remain the guardians and decision-makers for their children in out-of-home placement. Parents do not “sign away” their parental rights in these situations. Although parents are

the legal decision-makers, there may be limits on the choices parents can make regarding certain types of care for their children based on regulations or facility policy. People who are unable to make their own decisions at the age of majority must have guardians; usually, parents seek guardianship in this situation. Unfortunately, some parents abandon their children by not participating in decision-making and being unavailable for consent. In these cases, the facility must work with state child welfare agencies or, for individuals over the age of majority, with adult protective services or other agencies. There are some families who fulfill the responsibility for consent and decision-making although they are not involved in their children’s lives and do not visit them. Some children who are wards of state child welfare agencies also may be admitted to residential care, such as in situations in which the disability is the direct result of child abuse.

EFFECTS OF PLACEMENT

Baker and Blacher²⁷ evaluated the effects on the family of the placement of a family member with IDD into residential care. The vast majority of families reported that the placement had advantages for all involved. However, although parents of children younger than 15 years visited more frequently, they also reported the highest stress as well as the lowest marital adjustment and advantage to placement. Another study found no significant negative effect on adolescent siblings when a child with an intellectual disability resided outside the family home. The child with intellectual disability also continued to have an influence on family functioning, regardless of the place of residence.²⁵ Hostyn and Maes¹⁰ found that parents generally did not regret their decision to place their child into a residential setting.

Despite the benefits to family life that some have reported after placement in a residential setting, the decision for placement is extremely difficult for families to make.²² The family quality of life before and after placement also has been explored.²⁸ Overall, there were positive changes in the areas of emotions, freedom, and family relationships, although most parents reported continuing guilt and worry.

DURATION OF PLACEMENT

Because parents or guardians retain their parental rights, they may also terminate the placement and take their child home. This action sometimes occurs because parents regret their decision. It may also occur after a change in family circumstance, such as improved financial situation, change in marital status, or ability to access more community supports. In addition, it can occur because of changes or improvement in the child's condition (eg, tracheostomy care no longer needed).

When a child or youth returns to the family home, it is crucial to provide careful discharge planning that includes teaching parents or guardians and determining that they are ready to provide needed care. Important considerations for providing comprehensive home care for medically complex children and adolescents are necessary, as outlined in the previously published policy statement.²⁹ In addition to family training, arrangements need to be made for appropriate nursing services, home modifications, equipment, and transition to a new school program and therapy services.

WHO PROVIDES MEDICAL CARE FOR CHILDREN AND ADOLESCENTS IN RESIDENTIAL CARE?

There are federal regulations regarding the frequency of medical examinations in SNFs,³⁰ although there are no standards for medical directorships

or consultancies in these settings or for intermediate care facilities providing care for people with developmental disabilities. Medical directors can be pediatricians, neurologists, family physicians, or other medical specialists. Some facilities are part of a chain; there may be a single physician or a team of physicians with responsibilities for all the facilities. Some children and adolescents might continue to obtain routine or specialized medical care from their providers before placement. Some facilities have consulting arrangements with other specialists (eg, regular orthopedic, pulmonary, neurology, or rehabilitation medicine clinics on site), and others do not. Some may have arrangements with local acute care or specialty hospitals for inpatient care for children.

It is important for physicians acting as medical directors, primary care physicians, and consultants for children in residential placement to be familiar with their patients' specific medical conditions, which can include extremely rare disorders. They should also be familiar with the frequent complications of severe disability, including progressive respiratory insufficiency, severe musculoskeletal problems, complex seizure disorders, the requirement for tube feeding, and other gastrointestinal disorders. Physicians who act as medical directors should also understand their responsibilities as they relate to policies, procedures, and compliance with local laws, regulations, and regulatory agencies. They should understand internal and external administrative structure and responsibilities, which includes understanding of policy development with regard to safety, infection control, awareness of abuse/neglect by families or employees, reporting responsibilities, consent for treatment requirements, and other issues. Knowledge

and familiarity with issues related to palliative care and end-of-life decision-making are also an integral part of physician responsibilities.¹²

FINANCIAL SUPPORT FOR RESIDENTIAL PLACEMENT

Federal and state funds may be available to support children with severe disabilities and special health care needs to remain at home.³¹ However, it has also been noted that families of children with disabilities have disproportionate out-of-pocket expenses for the care of their children compared with the general population despite public and private insurance coverage, with lower-income families experiencing the most financial burden.^{32,33}

There has been a significant increase in federal funding to provide community support for children and youth with IDD and/or special health care needs, with diminished support for institutional settings. Additional funds for community support are sometimes provided by states, counties, and municipalities.³¹ Most children and adolescents residing in out-of-home settings become eligible for Medicaid, which continues to be a major supporter of care in SNFs across the life span. Although Medicaid coverage for SNFs for those younger than age 21 is optional for states, all states provide this benefit.³⁴ Supplemental Security Income (SSI) of children in SNFs is directed to the SNF for their care, because that is where they live. This policy is often surprising to families who have come to rely on the SSI as part of the family's income. Settings classified as schools or transitional settings do not access the child's SSI. A child with his or her own assets (eg, insurance settlements, inheritances) may not be eligible for public benefits. Private family medical insurance may also be accessed for some services,

such as therapy or care provided outside the SNF, but very few, if any, private insurance policies pay for skilled care placements. The Patient Protection and Affordable Care Act (Pub. L. 111-148) was passed in March 2013, with provisions to improve information accessibility to consumers, emphasize quality assurance and performance improvement, and prevent abuse in nursing homes.³⁵ However, payment for SNFs has not fundamentally changed under this law.³⁶ Because there may be variability in types of funding, each facility has personnel who understand funding sources and billing and should be able to provide that information to families. Educational programming for children and youth in out-of-home settings is generally funded by the school district in which the family lives. If a child attends a residential school because, as part of the individualized education plan process, the local school district has determined that it cannot meet the child's needs in a less restrictive placement, the school district may be responsible for paying for the residential services as well as the educational component. Families, even those with limited resources, may benefit from consultation with a professional skilled in financial planning and estate planning to learn how to maximize public benefits and preserve their ability to provide care and opportunities for all of their children.

Just as funding for home care is precarious in type, amount, and timing, funding for residential care also is limited. Because skilled care facilities must provide care within a strict limit of per diem Medicaid payments, they may decide that the more medically fragile children cannot be cared for adequately for the allowed amount of money. These limitations can lead to situations in which children who need more highly skilled care (eg, ventilation,

dialysis, total parenteral nutrition) will not be accepted for admission and therefore must be cared for at home, with parents providing much of the care with less supervision and fewer physical accommodations and resources than would be possible in an SNF. In essence, the parent provides unpaid skilled care at home, which, supplemented by funded home health care, provides a higher level of care than can be provided in a nursing home. In other situations, children remain in acute care hospitals for long periods of time, sometimes years. Some nursing homes raise money through philanthropy, which can supplement per diem payments for services. Nursing homes may be either for-profit or not-for-profit, and these differences can result in different payment, staffing, and other service provision.

FAMILY SUPPORT IN THE MEDICAL HOME

Families of children with significant IDs and/or special health care needs require support to obtain services, navigate complex systems of care, understand care options, and be supported in making difficult decisions that involve the entire family. The perception that professionals, such as primary care providers, expect families to care for their children at home, coupled with the lack of available support and resources, has been noted to be a source of frustration to families.²⁰ Hostyn and Maes¹⁰ also found that, even with provision of "family support," many families do not feel as if all their needs are being met. Caring for children and youth with complex needs and their families requires ongoing commitment from the primary care physician and the subspecialists who may be providing the majority of the child's medical care. Support from other health professionals, such as social workers,

can provide additional needed assistance to both families and the primary care provider. The support needed will change over time as the child's condition changes and as the family's understanding and relationship with their child evolve and grow. Ideally, the medical home model should provide this type of support; however, there are circumstances in which some parents need more care than can be provided from the medical home and in the community, given the current state of available resources.

CONCLUSIONS

Despite the fact that considerable progress has been made to support children with significant developmental and/or medical problems in the home setting, there continues to be a need for other options of care and living arrangements. The decision to have a child live away from the family home is difficult and complex. Although consideration must be given to providing each child with the best resources and support as possible, the family's needs, stressors, capacity, and relationships must also be considered. The importance of trying to support families to care for the child at home cannot be overstated. However, parents of children with significant special health care needs may, at some point, consider out-of-home placement.

GUIDANCE

1. Pediatricians who care for children and youth with medically complex needs or severe disabilities should, as part of medical home services, be aware and knowledgeable of community supports for these families. This assistance includes familiarity with respite services, programs available to provide nursing or supportive care in the

home, and financial supports for families. State or local agencies with responsibilities for health or developmental disabilities services function as potential sources of information for families and physicians. Agencies such as The Arc (www.thearc.org) and Family Voices (www.familyvoices.org) serve as strong resources for families and medical providers. Many other national resources, such as the National Dissemination Center for Children with Disabilities (www.nichcy.org) and Disability.gov (www.disability.gov), also are helpful.

2. Pediatricians should encourage parents and caregivers to take short breaks and avail themselves of respite services. If a parent appears to be overwhelmed, anxious, or depressed, the pediatrician should express concern and be instrumental in finding support for the parent.
3. Pediatricians should consider consultation with subspecialists who have experience in the longitudinal care of children with special health care needs for assistance with developing home care plans and consideration of long-term care options. These subspecialists might include neurodevelopmental disabilities pediatricians or child neurologists, developmental/behavioral pediatricians, specialists in the child's primary specific disorder (eg, pulmonologists, pediatric physiatrists), or palliative care specialists.
4. Physicians should respect the family's motivation to ensure compassionate, skilled, and medically appropriate care for their child regardless of the setting in which it takes place. A decision to place a child in out-of-home care may be seen as analogous to a family's decision that a child may live with

relatives or attend a boarding school. If a family wishes to consider the option of out-of-home care, the pediatrician should explore the reasons the family is contemplating placement. This type of inquiry also provides an opportunity to revisit the parents' understanding of the child's condition, prognosis, and goals of care and whether the treatment plan is consistent with those goals.

5. Information about care options for children with complex medical problems and IDD is often available through the state health department and/or the state developmental disability agency. The physician can then learn about local facilities and the process for application and provide assistance in this process, as needed. Social work assistance, if available, can assist in accessing information and providing support to families. Personnel from the state agency responsible for screening patients referred for placement should also be available as a resource. They often require an update on the child's medical condition, including up-to-date immunizations, physical examinations, vision and hearing assessments, screening for infectious conditions, a recent psychological assessment, and some laboratory examinations for consideration of admission.
6. The pediatrician should advise the family to visit all the possible facilities being considered, learn about the medical care provided within the facilities, meet the actual direct care providers, and make certain that the facilities meet all the state guidelines. Families of children who are living in the facilities can be excellent sources of information. Office- and hospital-based social workers also may be able to

provide additional support and information to families.

7. The pediatrician should remain available to resume care of the child when he or she is home for visits or returns home on a permanent basis and be available to the medical and nursing staff of the facility when the child is a new resident and the caregivers are not yet familiar with the child's usual condition. Some pediatricians may also continue to provide primary care for the child in a residential setting. It is important that lines of communication be clear; the facility might have policies that restrict orders to the medical director or nursing home medical staff. Direct, concise, person-to-person communication from the primary pediatrician chosen by the parents and medical director of the facility is crucial if shared care is desired by the parent and agreed to by the pediatrician and the medical director of the facility. A portable medical summary, as discussed in the AAP policy statement on transition,³⁷ provides an important mechanism to share medical records. Support for the parents' efforts to ensure safe, compassionate, and adequate care for their child is crucial. The support needed by the family is likely to change over time as the parents' role as direct caregivers diminish and as the child matures and his or her needs also change.
8. Pediatricians may find it useful to educate themselves about local, state, and/or federal issues to support children and youth with complex medical and developmental needs. Pediatricians, individually and through the national and state chapters of the AAP, can endorse policies and legislation that support funding programs for children

with special health care needs and their families. Policies that support children and adolescents who are medically fragile or have disabilities should recognize the diversity in this population, their families, and the communities in which they live. Additional studies are needed to better evaluate the different models of care, health and developmental outcomes of children and youth who have lived or are living in residential care, options available to children who leave or age out of home care, and quality indicators in SNFs. Pediatricians should be involved in the development of policies that guide medical care for children and adolescents in all settings and should advocate for registries of those living in congregate care settings.

9. If parents require assistance exploring issues about guardianship,

health care proxy, or power of attorney as a child reaches the age of majority, pediatricians can refer to The Arc for basic guiding principles (www.thearc.org/page.aspx?pid=2351). Because there is variability based on the state in which a family resides, families may also need to seek the assistance from state disability agencies and legal counsel.

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Patient- and Family-Centered Care Coordination: A Framework for Integrating Care for Children and Youth Across Multiple Systems

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- *Policy Statement*

POLICY STATEMENT

Patient- and Family-Centered Care Coordination: A Framework for Integrating Care for Children and Youth Across Multiple Systems

COUNCIL ON CHILDREN WITH DISABILITIES and MEDICAL
HOME IMPLEMENTATION PROJECT ADVISORY COMMITTEE

KEY WORDS

care coordination, family-centered care, patient-centered care,
medical home, patient-/family-centered medical home, PFCMH

ABBREVIATIONS

ACO—accountable care organization

CPT—*Current Procedural Terminology*

ED—emergency department

EHR—electronic health record

PFCMH—patient-/family-centered medical home

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abstract

FREE

Understanding a care coordination framework, its functions, and its effects on children and families is critical for patients and families themselves, as well as for pediatricians, pediatric medical subspecialists/surgical specialists, and anyone providing services to children and families. Care coordination is an essential element of a transformed American health care delivery system that emphasizes optimal quality and cost outcomes, addresses family-centered care, and calls for partnership across various settings and communities. High-quality, cost-effective health care requires that the delivery system include elements for the provision of services supporting the coordination of care across settings and professionals. This requirement of supporting coordination of care is generally true for health systems providing care for all children and youth but especially for those with special health care needs. At the foundation of an efficient and effective system of care delivery is the patient-/family-centered medical home. From its inception, the medical home has had care coordination as a core element. In general, optimal outcomes for children and youth, especially those with special health care needs, require interfacing among multiple care systems and individuals, including the following: medical, social, and behavioral professionals; the educational system; payers; medical equipment providers; home care agencies; advocacy groups; needed supportive therapies/services; and families. Coordination of care across settings permits an integration of services that is centered on the comprehensive needs of the patient and family, leading to decreased health care costs, reduction in fragmented care, and improvement in the patient/family experience of care. *Pediatrics* 2014;133:e1451–e1460

The medical home is the standard of care for all children and adults.^{1–3} The patient-/family-centered medical home (PFCMH) is well positioned to provide coordinated, compassionate, family-centered health care by forming strong links among the primary care provider team, specialist team, nurses, social workers, educators, hospitals, and other health care facilities where patients access services with their family/caregivers and community providers.⁴

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Care coordination is a “cross-cutting system intervention”⁵ that is “the deliberate organization of patient care activities between ≥ 2 participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.”⁶ Within the context of a high-performing medical home model focused on addressing family-centered needs, care coordination is paramount in developing and fostering partnerships across various settings and communities.⁷

Successful care coordination takes into consideration the continuum of health, education, early child care, early intervention, nutrition, mental/behavioral/emotional health, community partnerships, and social services (as well as payments for these services) needed to improve the quality of care for all children and youth including those with special health care needs, while acknowledging the importance of language and culture in achieving desired outcomes.⁸ It is to be distinguished from disease or case management, which primarily focuses on patients’ medical issues. Case managers work with and guide services intrinsic to their specific agency, often within the constraints of eligibility criteria. In contrast, care coordinators work with and guide the team process, which includes and is driven by the needs of patients and families for services across the community.⁹ These functions include care planning and building collaboration/partnerships with all medical and nonmedical providers working with a patient/family.¹⁰ Rather than focus-

ing on titles (eg, patient navigator, care coordinator, case manager), it is critical to focus on competencies, job descriptions, and functions in the physician-led team caring for the patient and his or her family in and outside the PFCMH.¹¹

NEW INFORMATION AND POLICY DEVELOPMENTS

The American health care system is being challenged to reduce costs of care while improving quality outcomes. A key component of recent legislative and regulatory efforts to achieve these savings includes the redesign of systems of care, building on robust medical and health care homes for both children and adults.¹² One method of achieving these financial outcomes is the reduction in care fragmentation and inefficiency within and across health systems. Fragmentation of care can be addressed with care coordination: “a patient and family centered, assessment driven, team based activity designed to meet the needs of children and youth while enhancing the caregiving capabilities of families.”¹³ Care coordination has been characterized as the set of activities that occurs in the space between providers, visits, and entities.¹⁴ Ultimately, coordination of care enables the achievement of the “triple aim” (better care, better health, and lower cost), a principal outcome for health system transformation.¹⁵

Although adult and pediatric health care organizations underscore common elements of the medical home (which includes care coordination across systems), there are intrinsic differences in their respective systems.¹⁶ The “Five Ds” that distinguish pediatric from adult medical home models are as follows: developmental trajectory, dependency on adults, differential epidemiology of chronic disease, demographic patterns of poverty

and diversity, and overall dollars spent on children versus adults.¹⁷ Another key differentiation is the inclusion and importance of family input in all aspects of coordinated pediatric care. A recent Institute of Medicine report provides 10 key recommendations for high-quality health care, including 1 emphasizing the integral role of the family: “involve patients and families in decisions regarding health and health care, tailored to fit their preferences.”¹⁸ Thus, it is essential that “family” is included in the “patient”-centered care model.¹⁹ As such, we refer to this model as the “patient/family-centered medical home” (PFCMH).

Payment for care coordination services has had limited success over the past decade. The American Medical Association added codes 99487–99489 to its *Current Procedural Terminology* (CPT) manual for care coordination for patients with complicated, ongoing health issues within a medical home, accountable care organization, or similar model.²⁰ The inception of these codes allows physicians to document and bill for coordinating care between community service agencies, linking patients to resources, supporting the transition of patients from inpatient to other settings, and working to limit so-called preventable readmissions.²¹ Pediatricians need to advocate for recognition of the codes via third-party payers in their respective regions.

The multidisciplinary framework outlined in Fig 1 offers a definition of care coordination and articulates its essential activities and competencies. Pediatric care coordination highlights the role of the patient- and family-centered care and team-based activities designed to meet the needs of children and youth. Care coordination addresses interrelated medical, dental, social, developmental, mental health, educational, and financial needs

PEDIATRIC CARE COORDINATION FRAMEWORK

Care Coordination Definition:

Pediatric care coordination is a patient- and family-centered, assessment-driven, team-based activity designed to meet the needs of children and youth while enhancing the care giving capabilities of families. Care coordination addresses interrelated medical, social, developmental, behavioral, educational and financial needs to achieve optimal health and wellness outcomes.

Defining Characteristics of Care Coordination

- | | |
|--|--|
| 1. Patient and family-centered (PFC) | 3. Promotes self-care skills and independence |
| 2. Proactive, planned, and comprehensive | 4. Emphasizes cross-organizational relationships |

Care Coordination Competencies:

- 1) Develops partnerships
- 2) Proficient communicator
- 3) Uses assessments for intervention
- 4) Facile in care planning skills (PFC)
- 5) Integrates all resource knowledge
- 6) Possesses goal/outcome orientation
- 7) Approach is adaptable and flexible
- 8) Desires continuous learning
- 9) Applies solid team/building skills
- 10) Adept with information technology

Care Coordination Functions:

- 1) Provide separate visits and CC interactions
- 2) Manage continuous communications
- 3) Complete/analyze assessments
- 4) Develop care plans (with family)
- 5) Manage/track tests, referrals, and outcomes
- 6) Coach patient/family skills learning
- 7) Integrate critical care information
- 8) Support/facilitate all care transitions
- 9) Facilitate PFC team meetings
- 10) Use health information technology for CC

FIGURE 1

A framework for high-performing pediatric care coordination. (Reproduced with permission from Antonelli R, McAllister J, Popp J. *Developing Care Coordination as a Critical Component of a High Performance Pediatric Health Care System: Forging a Multidisciplinary Framework for Pediatric Care Coordination*. Washington, DC: The Commonwealth Fund; 2009.) CC, care coordination.

to achieve optimal health and wellness outcomes.¹³

BENEFITS OF AND EVIDENCE FOR CARE COORDINATION

Simply put, care coordination improves outcomes (eg, health care utilization, family functioning/satisfaction, and finances). In a 2009–2010 National Survey of Children with Special Health Care Needs, 43% of parents reported receiving care coordination, as opposed to 47% in the 2005–2006 iteration of the survey.²² These data, which suggest a decrease in receipt of care coordination services over time, warrant further examination. Data analyses from the 2005–2006 National

Survey of Children with Special Health Care Needs revealed positive associations between care coordination, family-provider relations, and family/child outcomes. Specifically, the provision of care coordination was positively associated with patient- and family-reported “receipt of family-centered care,” resulting in “partnerships with professionals, satisfaction with services, ease of getting referrals, lower out of pocket expenses and family financial burden, fewer hours per week spent coordinating care, less impact on parental employment, and fewer school absences and ED visits.”²³

An Illinois study showed that children, youth, and their families had a higher

need for care coordination when communication between health care providers was inadequate.²⁴ Care coordination within primary care pediatric practices is associated with decreased unnecessary office and emergency department (ED) visits, enhanced family satisfaction, and reduced unplanned hospitalizations and ED visits.^{25–27} According to research in New Orleans, families of children and youth with special health care needs in an underserved population experienced enhanced services from nurse care coordinator support.²⁸ In short, fewer unmet needs for services ensue when primary care clinicians are sensitive to the culture and needs of children and youth with special health care needs and their families and incorporate levels of care coordination in care delivery.²⁹ Care coordination conducted as a standard of pediatric practice resulted in increased family satisfaction with the quality of care and also decreased barriers to care.³⁰ Other data have suggested that the PFCMH represents a process of care that may help families manage the daily demands of caring for children with special health care needs through family-centered care, provider-to-provider communication, and provision of care coordination.³¹ A 2011 study in children and youth with special health care needs and their families who received care coordination and individualized care plans via a Medicaid managed care plan study reported improved satisfaction with mental health services and specialized therapies and participants were observed to have a decline in unmet needs, improved satisfaction with specialty care, and improved ratings of child health and family functioning.³²

In a busy medical practice, care coordination fosters improved productivity and efficiency by transferring the mechanics of follow-up care,

referrals, equipment acquisition, letters of medical necessity, patient information, transition of care, and previous authorization to care coordinators rather than physicians. As such, efficiency ensues because physicians can spend less time on nonclinical issues for patients.

IMPLEMENTING CARE COORDINATION IN TRANSFORMED SYSTEMS OF CARE

Quality improvement processes are essential in the transformation to health care delivery models that support care coordination. However, it is critical to recognize that broad implementation of care coordination requires consideration of financing models, workforce development, and the development and implementation of tools supporting the provision of care coordination.³³ The costs of care coordination are not directly reimbursable under many traditional payment models, such as fee-for-service, despite evidence of reductions in health care costs.^{29,34,35} The most recent CPT manual includes codes for care coordination and transition services.²⁰

Health information technology can play a pivotal role in care coordination. Electronic tools can facilitate information sharing among patients/families and their health care teams, and subsequently, health care teams, community partners, and medical and nonmedical providers. For example, previsit summaries, comprehensive health care plans, medical summaries, and personal health records can be shared with, among, and between partners and health care teams caring for patients.⁹

Tracking and monitoring patients via the use of patient registries can support care coordination activities and functions and improve patient safety.⁷ These registries can be incorporated

and supported via electronic health records (EHRs) and other software tools with some adaptation. This technology is still evolving with “meaningful use” criteria of EHRs. Meaningful use is intended to use certified EHR technology to improve quality, safety, efficiency, and accountability; reduce health disparities; engage patients and families as partners; improve care coordination and population and public health; and maintain privacy and security of patient health information.³⁶ Ultimately, it is hoped that meaningful use compliance will result in better clinical outcomes, improved population health outcomes, increased transparency and efficiency, empowered patients/families, and more robust research data on health systems.³⁶ Interoperability of registry functionality and care plans with team members outside of the medical arena, but still in the medical and community “neighborhood” caring for a child, is critical. Care planning includes the use of an “actionable” care plan with assigned tasks/roles, a care plan document, an emergency information form, and/or a medical summary, including past medical history and salient specialist information.⁷ These care plans are developed and implemented with input from members of the team caring for a child, including community partners, educational specialists, primary care providers, dental providers, medical subspecialists and surgical specialists, and, most importantly, the family and patient themselves. Coordinated care plans are used across the continuum of care by including medical, educational, mental health, community, and home care provider input.³⁷ These plans should explicitly state goals with therapeutic (including early intervention) educational/vocational and family interventions to maximize outcomes

for children and youth with special health care needs and to drive successful transitions to adult systems of care. It is essential that care plans are maintained and updated with timely and salient information from all partners to avoid duplication of services and to optimize care for patients. Health care teams are essential to the provision of coordinated care. Teams include, but are not limited to, the patient/family, primary care providers, community partners/agencies, mental health care providers, educational systems, medical subspecialists and surgical specialists, urgent care/ED centers, nurse practitioners, physician assistants, dietitians, child care centers, nursing staff, social workers, therapists, home visitors, and other medical staff. Team building starts with establishing teams of physicians and ancillary staff and working with patients, families, and communities to coach patients/families to optimize their health care and chronic condition management.³⁸

“Relational coordination” is an emerging topic highlighting the fact that coordination is not merely management of the interdependence between tasks but addresses management of the people who are performing tasks. It is defined as “a mutually reinforcing process of interaction between communication and relationships carried out for the purpose of task integration.”³⁹ This concept is particularly relevant to care coordination for children and youth, because care coordination “activities” are as important as the team (eg, families, community partners, physicians, nurses, mental health providers, social workers) performing those activities. Relational coordination values the quality of communication (eg, care plans and meetings) and the quality of relationships between families, patients, providers, and partners.

Internet-based tools can optimize communication between families and providers, provide information, support skills training, allow networking among families, facilitate connections between health care providers and community partners, and elicit patient feedback about care. Comanagement with specialists ensures high quality of care and fosters communication across disciplines for patients with multiple diagnoses.⁴⁰ Also, care coordination augments reciprocity of patient information with transfer across settings (eg, from inpatient to outpatient settings). As health care system redesign evolves, it is critical that practitioners are cognizant of tools and organizations providing resources for care coordination. Several national organizations incorporate standards on care coordination structure, process, and outcomes. Table 1 shows a variety of such organizations and tools.

Given this rapidly changing and innovative landscape, it is imperative to continue education on care coordination, the PFCMH, accountable care organizations (ACOs), and family-centered and -driven health care for practicing physicians, medical students, resident trainees, nurses, nurse practitioners, physician assistants, mental/behavioral health practitioners, and social workers. This workforce training goal can be accomplished through maintenance of certification, continuing medical education, continuing education units, and curricula/competency changes in training. Education of the workforce is critically important, because care coordination functions and family-centered principles must be learned and cultivated. The training of current and future physicians on the value and pragmatic adoption and implementation of care coordination is paramount in ensuring its success in practice. The Accreditation

Council for Graduate Medical Education has selected a care coordination milestone as a key competency in the semiannual assessment of residents in its "Next Accreditation System,"⁴¹ which shows a fundamental commitment to training the next generation of physicians in care coordination. In addition, a Care Coordination Curriculum (funded by the US Maternal and Child Health Bureau) is now available to support the education of care coordination providers. This care coordination curriculum is designed to help fill the void of inadequate training opportunities for care coordinators presently. The target audience for this curriculum includes families and patients as well as physicians, nurses, social workers, and administrative staff. Essentially, it provides a framework for the evolution of team-based patient- and family-centered care coordination. It is currently being used in several state programs and delivery systems working to create care coordination capacity.⁴²

CARE COORDINATION AND ACCOUNTABLE CARE

ACOs are expected to play a key role in achieving the outcomes of the "triple aim."¹⁵ The Medicare Payment Advisory Commission has defined ACOs as "a set of providers associated with a defined population of patients, accountable for the quality and cost of care delivered to that population."⁴³ ACO providers could include a hospital, a group of primary care providers, specialists, and possibly other health professionals who share responsibility for the delivery of the highest quality care at the lowest appropriate cost. Key elements of accountable care include payment reform, performance measurement and accountability, and coordinated continuum of care. In the ACO model, there are incentives to manage health care utilization and

improve quality with shared savings to control cost. The PFCMH model can be enhanced through the ACO model with greater organization, coordination, and integration throughout the care system; yet, defining accountability within and across systems will be a formidable challenge.⁴⁴ One must begin with the premise that, from the perspective of the patient and family, care integration means that seamless and coordinated health care services are delivered across the entire care continuum, irrespective of institutional and departmental boundaries.⁴⁵

Implementing the activities of care coordination, with explicitly articulated roles and responsibilities for all members of the care team, will be foundational to the success of ACOs. The recommendations of a national expert panel tasked with defining the core elements of accountable care for children are presented in Table 2. These elements emphasize the unique needs of children and the role of care coordination in their health care delivery system.

IMPLEMENTATION

Pediatricians are encouraged to provide and partner with the PFCMH team in the office setting to manage patients and work with families and community partners across systems.³⁵ The Care Coordination Measures Atlas, developed by the Agency for Healthcare Research and Quality, provides a list of activities proposed as a means of achieving coordinated care that are organized by domains and perspectives (patient/family, health care professional, system representative) and can be a useful tool in achieving these aims.⁴⁶ There are several organizations that promote medical home and care coordination resources and tools. Table 1 summarizes several organizations, Web sites, and tools available to support those providing

TABLE 1 Care Coordination Tools and Organizations Supporting Care Coordination

Tool/Organization	Developer(s)	Description	Link(s)
Patient-Centered Medical Home (PCMH) Recognition Program	The National Committee for Quality Assurance (NCQA) (with input from the 4 primary care specialties)	"Gives practices information about organizing care around patients, working in teams and coordinating and tracking care over time"; specific elements covered including "Tracking and coordinating care" in the patient-centered medical home	http://www.ncqa.org/Programs/Recognition/PatientCenteredMedicalHomePCMH.aspx http://www.ncqa.org/Portals/0/Programs/Recognition/PCMH%202011%20Scoring%20Summary.pdf
Medical Home System Survey (MHSS)	National Quality Forum (NQF)	Focuses on improved patient care and addresses communication, transitions, health care home/PFCMH proactive plan of care and follow-up, and information systems	Requires log-in
The Patient-Centered Primary Care Collaborative (PCPCC)	Multistakeholder coalition of employers, consumer groups, health care providers	Invested in the advancement of care coordination theory and practice and PFCMH as described in recent publications	http://www.pcpcc.org/ ; http://www.pcpcc.net/video/care-coordination-and-patients-role-shared-decision-making-and-team-communication
National Center for Medical Home Implementation (NCMHI)	American Academy of Pediatrics (AAP)	Provides tools and resources for care coordination with specific supports, templates, and guides for pediatricians.	http://www.medicalhomeinfo.org/ ; http://www.aap.org/en-us/professional-resources/practice-support/Pages/Care-Coordination-Resources.aspx ; http://www.medicalhomeinfo.org/how/care_delivery/
TransforMED	American Academy of Family Physicians (AAFP)	Adult and pediatric medical home; TransforMED provides ongoing consultation, support, tools, and resources to physicians and practice leaders looking to transform their practices to a new model of care based on the concept of the PFCMH	http://www.transformed.com/resources/Continuity_of_Care.cfm
Medical Home Builder	American College of Physicians (ACP)	Adult medical home. Medical Home Builder is divided into self-paced modules on a variety of operational and clinical areas. Each of the modules contains background information, the ACP Practice Biopsy (a practice assessment tool), and links to the Resource Library, which includes relevant references and informative guides in a variety of formats including downloadable guides and policy templates.	https://www.practiceadvisor.org/home
Care Coordination Accountability Measures for Primary Care Practice	Agency for Healthcare Research and Quality (AHRQ)	This report presents selected measures from the Care Coordination Measures Atlas that are well suited for primary care practice. The selected measures are divided into 2 sets: Care Coordination Accountability Measures (from the patient/family perspective) and Companion Measures (from the health care professional and system perspectives; ie, self-assessment).	http://www.ahrq.gov/qual/pcpaccountability/pcpaccountability.pdf
Other National Medical Home recognition/accreditation programs	Provided by National Center for Medical Home Implementation (NCMHI)	Provides a list of additional programs offering medical home recognition, accreditation, and standards for interested practices and organizations	http://www.medicalhomeinfo.org/national/recognition_programs.aspx
Care Coordination Curriculum ⁴²	Boston Children's Medical Center; Maternal and Child Health Bureau	This curriculum, funded by the US Maternal Child Health Bureau can be used in training programs at the levels of local, state, national, delivery systems, and pediatric practices.	www.bostonchildrens.org/CareCoordinationCurriculum

TABLE 1 Continued

Tool/Organization	Developer(s)	Description	Link(s)
AAP Practice Excellence (APEX) Program	American Academy of Pediatrics	Guides physician practices through practice transformation into the PFCMH model of care. The APEX program is intended to provide knowledge, resources, and tools necessary to address practice transformation both efficiently and effectively.	http://www.aap.org/en-us/professional-resources/practice-support/APEX/Pages/The-Program.aspx

TABLE 2 Summary of Core Principles for Creating Accountable Child Health Outcomes

1. Child health care delivery has the potential to deliver both short- and long-term cost savings.
2. The epidemiology and treatment of chronic conditions in children are different than they are in adults.
3. Families are the drivers of child health.
4. Implementation of life-course approaches is essential for optimal child, adult, and population health outcomes.
5. Children's health care requires a diverse and complex network of nonmedical and medical stakeholders.
6. There is a strong need for well-defined care coordination and integration in children's health care.
7. Children represent a disproportionate segment of the population living in poverty, with large disparities among different subgroups.
8. Child health care quality measures require further development and specialized methods.
9. Payment for child health must incentivize stakeholders to provide elements of accountable care.

Source: unpublished data from SA Londhe, MHA, MA; N Sachedina, MBBS, MBA, MPP; M Mann, MD, MPH; S Wegner, JD, MD; RC Antonelli, MD, MS; March 12, 2012.

services to children and families. As health care reform implementation continues with delivery system changes and ACO evolution, pediatricians can work via their state's American Academy of Pediatrics' chapters, with children's cabinets in respective states/commonwealths, and with other inter-/intraagency state coordinating bodies to ensure that system changes support improved care coordination opportunities for meeting the needs of children and youth. Care coordination activities for implementation include the following:

- establishing formal responsibilities among team members and with the patient and family to comprehensively address patient needs;
- fostering strength-based relationships with families and children while building on existing strengths of patients and their family support systems;
- collaborating with all team members and providers involved in caring for a patient and family, including (but not limited to) medical subspecialists and surgical specialists, nurse practitioners, nurses, mental health care providers, social workers, dietitians, educators, community partners, child care centers, home visitors, and family networks;
- communicating across all systems (medical and nonmedical) involved in a child's care while adhering to Health Insurance Portability and Accountability Act rules and Family Educational Rights and Privacy Act regulations and consent driven by families and patients;
- facilitating transitions between entities (eg, pediatric/adult providers, community partners, hospitals, urgent/emergency care facilities, offices, specialists) and across time;
- assessing needs and establishing clear goals for the patient, family, health care team, and system;
- creating, implementing, and updating a formal written plan of care with family/patient input that is sensitive to their language, values, and culture; examples can be found at the National Center for Medical Home Implementation Web site (
- monitoring, following, and responding to needs and changes over time;
- supporting self-management goals as outlined by the team and patient/family;
- linking and collaborating with community resources and partners, including state Title V Children and Youth with Special Health Care Needs programs (eg, formal meetings, education collaborations, task forces, policy development meetings);
- fostering knowledge about community resources and linking families/patients to those resources commensurate with the needs of the patient, family, and population;
- using quality improvement strategies to facilitate implementation for the medical home team, staff, and partners (eg, EQIPP medical home course, APEX-AAP digital navigator) (see Table 1);
- visiting the National Center for Medical Home Implementation Web site (www.medicalhomeinfo.org)

for assistance and examples of support, resources, and templates in transforming clinical practice into a PFCMH;

- using health information technology and tools to facilitate care coordination^{7–9,40};
- advocating for adequate payment mechanisms for supporting care coordination (using CPT codes)^{20,21,26};
- ensuring ACOs and integrated delivery systems address and promote the integrity of the care coordination model (see Table 2)^{44–46};
- engaging with national organizations dedicated to quality measurement to ensure care coordination metrics and standards are appropriate to advance child health outcomes⁴⁷; and
- supporting efforts to develop practical implementation of care coordination algorithms in practice, practice management, and team development.

SUMMARY AND CONCLUSIONS

Care coordination should be a team- and family-driven process that improves family and health care practitioner satisfaction, facilitates children's and youth's access to services, improves health care outcomes, and reduces costs associated with health care fragmentation, which can lead to under- and overutilization of care. It is imperative that well-defined care coordination is integrated into children's health care. Tools for care coordination include health information technology, integrated health care teams, and Internet-based resources. Because of their foundational reliance on PFCMH, ACOs may support the delivery of high-quality, lower-cost care but only if explicit elements of care coordination are included in delivery

system design and training and resources are provided for care coordination.

RECOMMENDATIONS

1. Use and create mechanisms for patients/families to learn the skills they may need to be partners in their own care and in decision-making for optimal care coordination.⁴⁸
2. Ensure that the patient's and family's needs for services and information sharing (eg, care planning) across people, systems, and functions are met via (a) formal assessments, (b) infrastructure (eg, teams), and (c) tracking (eg, registries); this is crucial in operationalizing care coordination.⁴⁶
3. Continually involve the patient/family (eg, families as partners/advisors), build on the strengths of the patient/family, clearly delineate responsibilities of team members, and create careful handoffs when transitioning across settings (eg, between inpatient and outpatient settings and between pediatric and adult care providers or settings).^{46,49–51}
4. Use and develop efficient and accredited health information systems and information technology advances to foster successful transfer of information; to support collaborative communications between patients, families, and the care team; and to facilitate shared decision-making (eg, developing and using care plans).
5. Use care coordination across transitions between entities of the health care system (ie, between and among patient care teams, across settings, between caregivers, and between health care organizations) and with transitions over time (ie, across the

life span, between episodes of care, across trajectory of illnesses).^{49–51}

6. Ensure that comanagement and communication occur among specialists and primary care providers. This care model requires reciprocal and bidirectional communication (ie, secure e-mail, phone call, note, fax), which can be augmented, but not replaced, with health information technology.^{7,37}
7. Ensure ongoing education of elements of care coordination and the medical home for practicing physicians, nurse practitioners, physician assistants, nurses, medical students, resident trainees (across disciplines), mental/behavioral health care practitioners, social workers, and other health care professionals via specific training/curricula, continuing medical education programs, and publications.^{41,42}
8. Understand the landscape of the PFCMH and care coordination as they relate to national organizations and certification/standards, such as ACOs, the National Committee for Quality Assurance, the Patient-Centered Primary Care Collaborative, the National Quality Forum, quality metrics broadly, and health care reform, including financing of care coordination as well as remote collaborative services (eg, phone, e-mail consults with specialists, phone/e-mail encounters with families) that maximize the potential of children, youth, and families.⁴⁷
9. Collaborate with state Title V agencies and Maternal Child Health Block Grant applications ensuring that care coordination is incorporated and addressed and that best practices of care coordination models are emulated.

10. Understand and use new care coordination codes (99487–99489)²⁰ and advocate for payment of these care coordination services by payers.

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Pediatric Anthrax Clinical Management

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- *Clinical Report*

CLINICAL REPORT

Pediatric Anthrax Clinical Management

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KEY WORDS

anthrax, anthrax vaccine, biological weapon, bioterrorism, prophylaxis, children, pediatrics

ABBREVIATIONS

AAP—American Academy of Pediatrics
AIG—anthrax immune globulin
AVA—anthrax vaccine adsorbed
CDC—Centers for Disease Control and Prevention
CNS—central nervous system
CSF—cerebrospinal fluid
CT—computed tomography
FDA—US Food and Drug Administration
PCR—polymerase chain reaction
PEP—postexposure prophylaxis

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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Anthrax is a zoonotic disease caused by *Bacillus anthracis*, which has multiple routes of infection in humans, manifesting in different initial presentations of disease. Because *B anthracis* has the potential to be used as a biological weapon and can rapidly progress to systemic anthrax with high mortality in those who are exposed and untreated, clinical guidance that can be quickly implemented must be in place before any intentional release of the agent. This document provides clinical guidance for the prophylaxis and treatment of neonates, infants, children, adolescents, and young adults up to the age of 21 (referred to as “children”) in the event of a deliberate *B anthracis* release and offers guidance in areas where the unique characteristics of children dictate a different clinical recommendation from adults. *Pediatrics* 2014;133:e1411–e1436

INTRODUCTION

Bacillus anthracis is often placed at or near the top of potential threat agents by biodefense experts.^{1–3} Because of the potential use of *B anthracis* as a biothreat agent, clinical guidance that can be quickly implemented must be made available for review by clinicians before its use in a bioterrorism event, such as the intentional release of aerosolized spores. It is a rod-shaped bacterium present in the environment and may also exist in a spore form that is easy to disperse. It can remain a potential hazard for weeks to years after bioterror dispersal. Anthrax infection in humans can develop after exposure at different anatomic sites and can manifest in different clinical presentations, including cutaneous, inhalation, and gastrointestinal, all of which can disseminate and lead to meningoencephalitis. Another form of anthrax, injection anthrax, has recently been described in drug users and is associated with contaminated heroin use.⁴ This form of anthrax will not be addressed in this report. Most types of anthrax carry a high mortality, including cutaneous infection if local disease of the skin or mucosal surfaces is untreated and progresses to systemic disease.^{2,5,6} Toxins mediate much of the morbidity and mortality associated with *B anthracis*, including hemorrhage, edema, and necrosis.⁷

The potential danger of *B anthracis* as a bioweapon was dramatically illustrated after an accidental release of spores in 1979 from a military microbiology facility in Sverdlovsk, Union of Soviet Socialist Republics, that resulted in at least 77 cases of human anthrax and 68 deaths.⁸ However, none of the cases reported in this incident involved children. *B anthracis* was also used as a bioweapon in 2001, when spores were intentionally distributed through the US postal system. Of

the 22 resulting cases, 18 had confirmed anthrax, 11 of which had inhalation anthrax; 5 of these cases were fatal.⁹ The other 11 cases, both suspected and confirmed, were nonfatal cutaneous anthrax, 1 of which occurred in a 7-month-old infant, whose disease progressed to systemic illness.¹⁰

This document provides clinical guidance for the prophylaxis and treatment of children in the event of an intentional *B anthracis* release and offers guidance in areas in which the unique characteristics of children dictate a different clinical recommendation from that for adults. A comprehensive review of anthrax as it relates to naturally occurring infection is not provided. Rather, the document gives guidance on caring for children after an intentional release of *B anthracis* when public health officials are recommending prompt prophylaxis of individuals thought to be exposed and rapid treatment of individuals with potential anthrax infection. Guidelines for both treatment and prevention in adults have been developed and are not reviewed in this document.¹¹

Children require special considerations for prophylaxis and treatment, because the clinical presentation and progression of disease for cutaneous, inhalation, gastrointestinal, meningoencephalitis, and disseminated anthrax infection may be different from those in adults. For example, children could be at a higher risk of developing disseminated, systemic disease and/or meningoencephalitis after focal infection. It may be more difficult to diagnose the infection in children by clinical signs and symptoms early in the course, because febrile and respiratory illnesses, which may mimic early symptoms of anthrax, are common in children compared with adults. Furthermore, the signs and symptoms for any type of anthrax infection in infants younger than 2 months are not well defined.¹²

In addition, antimicrobial selection and clinical care may be different for chil-

dren. Young children, as well as children, adolescents, and young adults with disabilities, may have difficulty swallowing oral tablets; compliance also may be reduced with poor-tasting suspensions.¹³ The safety and tolerability of some antimicrobial agents when prescribed for children continuously for weeks to months are not well-studied.

Although the provision of antimicrobial agents and vaccine to asymptomatic children for postexposure prophylaxis (PEP) falls under the aegis of public health authorities, local health care providers should be familiar with available resources during a public health emergency to be prepared to treat symptomatic children (ambulatory and hospitalized) who present with focal or systemic infection. In addition, pediatric health care providers will likely receive questions about antimicrobial prophylaxis regimens from families and will be called on to provide reassurance and guidance to families, specifically regarding adverse effects of the prophylactic antimicrobial agents. Pediatricians and others who provide health care to children will be involved in this process as trusted sources of health care information for their patients and families. Clear lines of communication between clinicians and public health practitioners will help families receive consistent messages, improve disease surveillance and adherence to prophylactic antimicrobial regimens, decrease panic among parents and caregivers, and possibly save lives in the midst of a public health emergency.

The American Academy of Pediatrics (AAP) has developed a Pediatric Preparedness Resource Kit¹⁴ to encourage partnerships and joint decision-making between pediatricians and state and/or local health department representatives. This kit includes information and strategies that will help to promote strategic communications and effective messaging in a situation such

as a *B anthracis* release (see www.aap.org/disasters/resourcekit).

Information and guidance that is specific to the identified exposure after a bioterror release in which spores intentionally target civilians will be provided on the Centers for Disease Control and Prevention (CDC) Web site to assist pediatric health care providers with critical decision-making when dealing with patients, families, health care facilities, and local health departments (www.cdc.gov/anthrax).

This guidance reflects a comprehensive review of the literature and the opinions of individual experts from the AAP and the CDC (referred to as the AAP and CDC Pediatric Anthrax Writing Group) at the time of publication, based on the proceedings of a jointly sponsored workshop, held at the CDC Tom Harkin Global Communications Center in Atlanta, Georgia, in November 2012.

Guidance for pediatric anthrax clinical management is provided in Appendices 1 through 8, which are ordered based on severity of disease to offer easy access in the event of a public health emergency.

CLINICAL PRESENTATIONS OF ANTHRAX

B anthracis is an aerobic, gram-positive, encapsulated, spore-forming, nonhemolytic, nonmotile, rod-shaped bacterium. It causes an acute infection called anthrax that can manifest differently according to the route of exposure: cutaneous, inhalation, and gastrointestinal. Each of these forms can progress to systemic disease, which may present clinically with signs of septicemia with the subsequent development of meningoen- cephalitis.¹⁵

Exposure to aerosolized *B anthracis* is likely to result in a predominance of inhalation and cutaneous anthrax cases; however, gastrointestinal cases also may occur. The clinical presentations as discussed herein are primarily from

reports of anthrax in previously healthy adults. Different clinical presentations may occur across the spectrum of pediatric age groups and in special pediatric populations, such as those with underlying comorbidities or disabilities.

Cutaneous Anthrax

Approximately 95% of naturally acquired cases of anthrax are cutaneous. Clinical disease in children appears to be similar to adults, spanning the spectrum from localized to systemic disease.¹⁶ One of the youngest documented cases of cutaneous infection occurred in a 1-month-old infant who was hospitalized with *B anthracis* infection around the mouth, presumed to have been acquired from his mother with cutaneous anthrax.¹⁷

With cutaneous anthrax, after an incubation period of 1 to 12 days, the skin lesion progresses over 2 to 6 days from a pruritic papule or vesicle into a characteristic depressed black eschar surrounded by moderate to severe edema. The lesion is typically painless and can be accompanied by fever, malaise, headache, and painful lymphadenopathy.^{12,18} The mortality rate for cutaneous anthrax is less than 1% if treated with antimicrobial agents but can be as high as 20% if untreated.^{12,16,17,19} Those with symptoms or signs of systemic involvement or with lesions that involve the head, neck, or upper torso or that are large, bullous, multiple, or surrounded by significant edema have higher mortality rates.^{16,19}

Inhalation Anthrax

Inhalation anthrax has the highest case-fatality ratio of the typical forms of the disease. After being inhaled into the lungs, *B anthracis* spores are transported by macrophages and other phagocytic cells to regional lymph nodes, where either en route or on arrival they can germinate into toxin-producing bacteria. The bacteria and

toxins cause systemic anthrax. Spores may germinate as soon as 1 day or may remain dormant for weeks or months before germinating.^{20,21} Depending on the circumstances of exposure, the inhalation form of anthrax may be the most prevalent form of serious, life-threatening disease after an anthrax attack. The incubation period for inhalation anthrax in humans is not well-defined and has ranged from 1 to 43 days, which may reflect delayed germination of inhaled spores or repeated inhalation of spores from the environment after the original exposure event.⁸ Initial nonspecific signs and symptoms may include mild fever, fatigue, myalgia, and cough, and can resemble a viral respiratory illness.²² Occasionally, these prodromal signs and symptoms briefly improve before abrupt deterioration^{7,23,24} to a more fulminant disease characterized by diaphoresis, stridor, dyspnea, hypotension, or acute respiratory distress.^{7,20,23,25} These patients may develop sepsis accompanied by cyanosis, shock, and hemorrhagic pneumonia. Hemorrhagic pleural effusions often develop. Other organ systems, particularly the central nervous system (CNS), also can be affected secondary to bacteremia, a frequent occurrence in children noted with certain bacterial pathogens. The risk of meningoenitis is not well-defined in children, but in adults with systemic disease, it appears to occur in approximately 50% of cases.^{22,25,26}

In the 5 pediatric inhalation anthrax cases reported from 1900 to 2005, nausea, vomiting, headache, dyspnea, or meningeal signs were exhibited, and 3 of the 5 children died.²⁷ With prompt diagnosis, initiation of combination antimicrobial therapy, and modern critical care, the mortality rate observed in adults with inhalation anthrax dropped from more than 90% for the whole 20th century to 45% in the exposures linked to letters contaminated with *B anthracis* spores in 2001,²³ which suggests

that better outcomes are also likely to occur in children. In 2006²⁸ and 2011,²⁹ adults in Pennsylvania and Minnesota, respectively, were successfully treated for naturally acquired inhalation anthrax, demonstrating the effectiveness of modern treatments.

Gastrointestinal Anthrax

Gastrointestinal anthrax can occur after the consumption of food contaminated with *B anthracis* vegetative cells or spores. After an incubation period of 1 to 7 days after ingestion of bacilli or spores, gastrointestinal anthrax presents with signs and symptoms that can include severe abdominal pain and tenderness, nausea, vomiting, hematemesis, anorexia, and fever progressing to more severe systemic illness.^{20,30–32} With antimicrobial treatment, gastrointestinal anthrax exhibits a mortality rate of 40% or less.³¹

A report by Bravata et al²⁷ indicated that the most commonly reported pediatric gastrointestinal anthrax symptoms, in order from most to least common, were fever, abdominal pain, vomiting, diarrhea, and bloody stool.

Gastrointestinal anthrax also can manifest as oropharyngeal anthrax, which starts as a painless mucosal lesion in the oral cavity or oropharynx. Signs of oropharyngeal anthrax may include dysphagia with posterior oropharyngeal necrotic ulcers, unilateral neck swelling, cervical adenopathy, edema, pharyngitis, and fever. Gastrointestinal anthrax can progress to systemic infection.^{20,31}

Meningeal Anthrax

In contrast to bacterial meningitis attributable to organisms, such as pneumococcus, meningococcus, or *Haemophilus influenzae* type b, *B anthracis* causes a hemorrhagic meningoenitis that involves both deep brain parenchymal hemorrhagic lesions as well as infection of the cerebrospinal fluid (CSF) in the subarachnoid space. All forms of

systemic anthrax can progress to meningoen­cephalitis, which, to date, has been nearly always fatal.^{7,27} However, there is limited experience with treatment using currently available intensive care. In a systematic review of pediatric anthrax by Bravata et al,²⁷ meningoen­cephalitis developed in 7 of 22 patients with gastrointestinal anthrax and 1 of 37 patients with cutaneous anthrax; 6 children had primary meningoen­cephalitis with no apparent focus of entry. Only 1 patient survived. In an autopsy series of adult patients from Sverdlovsk, 50% of fatal cases had evidence of meningeal involvement.³³ Signs of meningoen­cephalitis include fever, altered mental status, meningeal signs, and seizures,³⁴ although in the review by Bravata et al,²⁷ pediatric cases of meningoen­cephalitis presented with fever, headache, delirium, seizures, emesis, and diarrhea. Too few cases exist to provide information on differences in the clinical presentation of meningitis between adults and children.

PEP TO PREVENT INFECTION

Studies have demonstrated that spores with the potential to germinate in vitro could be found in the lungs of non-human primates up to 100 days after inhalation exposure.³⁵ However, the potential for long-term spore survival in the environment or subsequent disease is unknown.³⁶ In the setting of a large-scale release of *B anthracis* spores, the public health response will focus on protecting the exposed population with PEP. The CDC Advisory Committee on Immunization Practices and the AAP Committee on Infectious Diseases recommend a combination of antimicrobial prophylaxis for immediate protection during the first 60 days after exposure and immunization for long-term protection after exposure to *B anthracis* spores.^{18,37} Antimicrobial prophylaxis and immunization in spe-

cial pediatric populations, such as those with underlying comorbidities or disabilities, may differ from those provided below.

Antimicrobial PEP

Similar to adults, all children believed to be exposed to aerosolized *B anthracis* spores should receive at least 60 days of antimicrobial prophylaxis (Appendix 1). In response to an anthrax release, local points of dispensing will be identified and coordinated by public health officials, and will receive, and subsequently dispense, an initial 10-day supply of oral ciprofloxacin or doxycycline (or, if pathogens are documented to be susceptible to penicillin, oral amoxicillin, or phenoxymethyl penicillin may be used). Clindamycin and levofloxacin are considered effective alternative antimicrobial agents. Providing antimicrobial prophylaxis to the local population within 48 hours of the initial exposure is the public health goal, with local supplies being supplemented by antimicrobial agents from other regional or national sources. In the early phases of the response, data gathered by federal and state public health officials will better define the exposed population within the 10 days after that particular exposure. To minimize indiscriminate prescribing and use of antimicrobial agents during the early phases of the response to an event, practitioners are advised to seek advice from local public health officials to determine those in need of PEP. Individuals deemed exposed to aerosolized *B anthracis* spores will be notified by local health authorities in partnership with local professional organizations and health care providers to receive the first dose of anthrax vaccine adsorbed (AVA [BioThrax, Emergent BioSolutions, Rockville, MD]), instructions for the second and third AVA doses, and an additional 50-day supply of antimicrobial agents. This 60-day antimicrobial regimen covers the incubation period of

the disease^{8,38} and provides protection until the vaccine confers immunity.

A limited supply of oral suspension formulations of recommended PEP antimicrobial agents will be available, and distribution strategies will be determined by public health authorities at state and local levels. If oral suspensions are not readily available, doxycycline tablets will be provided with clear directions, as recommended by the US Food and Drug Administration (FDA), on how the tablets can be crushed and added to a food or liquid to create a formulation that is more palatable and designed to improve adherence for those who are unable to swallow a tablet.³⁹

Tetracycline-based antimicrobial agents, including doxycycline, may cause permanent tooth discoloration for children younger than 8 years if used for repeated treatment courses. However, doxycycline binds less readily to calcium compared with older tetracyclines, and in some studies, doxycycline was not associated with visible teeth staining in younger children.^{40,41} Although no prospective data exist on staining of teeth in children younger than 8 years taking a 60-day course of doxycycline, the benefits of preventing life-threatening anthrax infection outweigh the potential risks of injury to teeth. Similarly, although no prospective data exist on the risks of cartilage toxicity with ciprofloxacin, particularly for a 60-day course, the benefits of an extended course for prophylaxis in children outweigh the concerns for potential cartilage toxicity. On the basis of availability, either antimicrobial agent may be used and should provide equivalent efficacy, although prospective data after *B anthracis* bioterror exposure in children do not exist.⁴² Some experts believe that if adverse events occurred with an equal incidence between doxycycline and ciprofloxacin, the potential for tooth staining as a sequela may be

less serious than the potential for long-term cartilage injury.

Additional liquid formulations, such as amoxicillin and liquid suspension forms of doxycycline and ciprofloxacin, may be available in this additional 50-day antimicrobial agent supply for infants and young children or children, adolescents, and young adults with disabilities after the initial 10-day prophylaxis supply has been completed and the antimicrobial resistance profile of the *B anthracis* strain has been determined.

Vaccine PEP

AVA contains proteins from a sterile, cell-free, culture fluid grown from a *B anthracis* strain and contains no live or dead bacteria. All exposed adults are expected to receive AVA intramuscularly or subcutaneously at 0, 2, and 4 weeks in addition to a total of 60 days of antimicrobial prophylaxis.¹¹ AVA has been shown to be safe and immunogenic in clinical trials in adults.³⁷ Serious adverse events after AVA administration in adults were infrequent. However, local adverse events, such as pain, erythema, induration, and swelling, were common.³⁷ Most of these local adverse events were not serious, and self-resolved. The vaccine, usually given as a 0.5-mL dose, contains 0.6 mg of aluminum (as aluminum hydroxide). A 0.5-mL dose of diphtheria, tetanus, acellular pertussis (DTaP [pediatric formulation] or Tdap [adolescent/adult formulation]) vaccine may contain up to 0.85 mg of aluminum. Local adverse events may be similar to those described in adults administered AVA and in children administered other vaccines, with similar aluminum hydroxide concentrations.

On the basis of routine and extensive use of similar vaccines in children 6 weeks of age and older, it is anticipated that AVA should demonstrate immunogenicity to *B anthracis* protective antigen necessary to provide protection against symptomatic infection in children

6 weeks and older. The safety profile should be similar to that in adults, commensurate with prevention of life-threatening infection. However, studies of AVA in children younger than 18 years have not been conducted, and the vaccine is not currently approved by the FDA for use in children. Until there are sufficient data to support FDA approval, AVA will be made available for children at the time of an event as an investigational vaccine through an expedited process that will require institutional review board approval, including the use of appropriate consent documents. Information on the process required for use of AVA in children will be available on the CDC Web site at the time of an event (www.cdc.gov/anthrax), as well as through the AAP and the FDA. All exposed children 6 weeks and older should receive 3 doses of AVA at 0, 2, and 4 weeks in addition to 60 days of antimicrobial chemoprophylaxis. The recommended route of vaccine administration in children is subcutaneous, although both subcutaneous and intramuscular injections appear to achieve similar levels of immunogenicity in 60 days. Children younger than 6 weeks should immediately begin antimicrobial prophylaxis but delay starting the vaccine series until they reach 6 weeks of age.

For children, a local adverse event to a previous dose of AVA is not a contraindication to receiving additional doses, although the subsequent dose should be administered at an alternate site. Large local reactions or systemic adverse events should be evaluated before additional doses are administered. Given the short time intervals between the 3 doses recommended for PEP, parental concerns about local adverse events should be addressed prospectively to increase the likelihood of adherence with the full vaccination schedule.

PEP use of AVA is not yet an FDA-approved indication in any population. The doses for each pediatric age group

that balance immunogenicity, safety, and protective efficacy have not yet been determined. Clinical guidance for use of AVA in infants and children is currently based on data from adult AVA clinical trials and expert opinion, although recommendations for pre-event limited investigation of AVA in children are under consideration. The Presidential Commission for the Study of Bioethical Issues recommends that pre-event pediatric research into medical countermeasures, including AVA administration, should pose only a minimal risk to children and should use an age de-escalation process to determine study participation risk.⁴³ This process would look at safety in 18-year-olds and then progressively assess safety and risk at younger ages. Studies that may cause “no more than a minor increase over minimal risk” will require national review under federal regulations. Local institutional review boards should be aware of their role, before a bioterror event, in facilitating the appropriate use of AVA in children during an event. Federal agencies are collaborating on ways to streamline the consent process in a public health emergency. The intent of all providers and federal agencies is to ensure that all children exposed during an event have appropriate access to vaccine.

Special Vaccination Considerations

AVA should not be coadministered routinely with standard childhood vaccines during an anthrax bioterror event. The coadministration of routine vaccines to children in addition to the recommended 3 doses of AVA within 6 weeks of the final AVA immunization could contribute to increased adverse reactions, resulting in a reduction in adherence to full vaccine schedules for both routine vaccines and AVA. In addition, research on the effect of anthrax vaccine on the immunogenicity of routine vaccines has not been performed. Infants and children who are

hospitalized yet still exposed during an anthrax bioterror event should be vaccinated by using the same schedule as outpatients. Given the host immune response normally documented with infection, those with anthrax infection may not require immunization, but systematically collected data on immunity after infection are not available; therefore, these children also should receive all 3 AVA vaccine doses.

Immunization of children exposed to aerosolized *B anthracis* spores with AVA is a priority, above routine immunizations. Although data are not available in children regarding the types and frequency of adverse events after immunization, or whether administering AVA as soon as a few days after the receipt of routine immunizations will lead to an increased frequency of adverse events, the benefits of AVA in children exposed to aerosolized *B anthracis* spores are currently believed to outweigh these risks.

Routine immunizations should resume 4 weeks after the last AVA dose.

INFECTION CONTROL IN THE HOSPITAL AND COMMUNITY

If patients have had recent exposure to aerosolized *B anthracis* spores, the risk of aerosolization of spores from clothing or skin and subsequent inhalation is unknown but not believed to be high.⁴⁴ Public health officials, in collaboration with the CDC, will issue recommendations, which will be available on the CDC Anthrax Web site (www.cdc.gov/anthrax), on how the public should decontaminate clothing and other surfaces after exposure, as well as how to decontaminate dwellings and public places where children may be present, such as schools and child care centers.

Human-to-human transmission of anthrax itself is exceedingly rare and described only in association with exposure to cutaneous lesions.⁴⁵ Trans-

mission through nonintact skin contact with draining lesions is possible; therefore, use Contact Precautions if a large amount of uncontained drainage is present. Cutaneous lesions will no longer contain vegetative bacilli within 24 hours of starting antimicrobial therapy.⁴⁶ Hand washing with soap and water is preferable to use of waterless alcohol-based antiseptics, because alcohol does not have sporicidal activity. Patient care itself does not appear to pose a risk for transmission to health care providers.⁴⁷ Although Standard Precautions for patient care and disposal of blood and potentially contaminated body fluids adequately address contagiousness from vegetative bacilli, the presence of spores in contaminated body fluids, dressings, and patient linens may require additional sanitizing or disposal measures. Incineration or steam sterilization (121°C for 30 minutes) will destroy spores. Advice on infection control measures that address the need for incineration or steam sterilization will be made, specific to an anthrax event, on the CDC Anthrax Web site (www.cdc.gov/anthrax).

Anthrax PEP is not required for health care workers or other patient contacts as a result of exposure to the patient. However, health care workers and other patient contacts might require PEP depending on other exposure risks. A private room is unnecessary, and Standard Precautions should be used for patient care, including patient transport.

MANAGEMENT OF PATIENTS WITH SUSPECTED AND CONFIRMED ANTHRAX

General Diagnostic and Treatment Considerations

Diagnosis

The initial evaluation of patients with any form of anthrax after a biological weapon exposure should be based on careful clinical examination and labo-

ratory testing of sites of presumed infection. A Gram stain is likely to be the only rapid method for identifying *B anthracis* readily available in a clinical laboratory. The organism is characterized as a gram-positive bacillus that forms long chains of vegetative cells with a "jointed bamboo-rod" appearance in culture or short chains of 2 to 4 cells in direct clinical samples. The organism can be isolated from specimen cultures of blood; skin; respiratory secretions; vesicular, pleural, or ascetic fluid; or stool, as well as from CSF (Appendix 7). Given the high rates of meningoenitis in children who have signs and symptoms of systemic anthrax, lumbar puncture should be performed as resources permit, unless clinically contraindicated (such as suspected increased intracranial pressure).²⁷ Gram-positive bacilli with typical morphology found on unspun peripheral blood smears or in vesicular fluid or CSF are highly suggestive of anthrax.¹⁵

Although most clinical laboratories can provide preliminary culture results, they may not be able to perform sophisticated confirmatory tests, such as polymerase chain reaction (PCR) assay on patient specimens (blood, serum, lesion swabs), lethal factor detection analysis, and immunohistochemical staining of tissue, which are available through local or state public health laboratories or the CDC. Public health laboratories in the Laboratory Response Network (www.bt.cdc.gov/Lrn/), a national network of local, state, and federal public health laboratories, can identify *B anthracis* by standard culture methodology in addition to other methods and can perform antibacterial drug susceptibility testing. For current information on the availability and types of traditional confirmatory tests, as well as newly developed molecular tests, that can be performed by public health authorities,

particularly during a biological weapon exposure, visit the CDC Anthrax Web site. (www.cdc.gov/anthrax/labs/labresearch.html).

Treatment

The production of toxins and the frequent occurrence of meningoen­cephalitis, as well as the presence of latent spores, must be taken into account when selecting antimicrobial agents and the duration of treatment of anthrax. Most of the data used to make these recommendations are based on historical information collected before availability of many of the antimicrobial agents discussed, in vitro studies, and limited nonhuman primate studies. Treatment data that are available almost uniformly come from adult patients. For many of the antimicrobial agents discussed herein, limited pharmacokinetic data are available to make dosing recommendations for anthrax, particularly for young infants and neonates. However, systemic anthrax can be a rapidly lethal disease in humans, so in the absence of compelling, well-documented adverse safety data in children, the most effective antimicrobial agents used in the adult population also should be made available for use in children. Children may require larger doses per kilogram of body weight and more frequent dosing for certain antimicrobial agents to achieve a therapeutic exposure equivalent to that documented to be effective for adults. The recommended doses must be sufficient to ensure a therapeutic antimicrobial exposure required for life-threatening infection (ie, doses that achieve adequate exposure in more than 98% of all children treated). Antimicrobial dosing regimens, both empirical and definitive, for all anthrax clinical presentations in children and neonates are provided in Appendix 2 (cutaneous anthrax without systemic illness), Appendix 3 (systemic anthrax to include inhalation and gastrointestinal infection, without

meningitis), Appendix 4 (systemic anthrax to include inhalation and gastrointestinal infection, with meningitis), and Appendix 6 (dosing in preterm and term neonates 32 to 44 weeks' postmenstrual age).

After an exposure to *B anthracis* aerosolized spores, patients treated for any form of anthrax are at risk for late-occurring inhalation anthrax from residual ungerminated spores that may remain in the lungs for several weeks or months after an inhalation event. Depending on the patient's immune status and age, as well as the type of antimicrobial agent used, some patients recovering from severe systemic disease will develop an immune response that would provide protection against germination of any remaining spores. However, if antimicrobial therapy is initiated early in the illness, the immune response may be blunted,⁵⁸ thus requiring continuation of antimicrobial therapy over several weeks to clear organisms as they emerge from the spore form. There is evidence that symptomatic nonhuman primates that are bacteremic with *B anthracis* and treated with antimicrobial agents for at least 10 days develop an immune response and do not develop clinical disease attributable to retained spores that germinate after discontinuation of antimicrobial therapy.⁴⁸ However, no data exist in either adults or children to identify which infected people may develop protective immunity and at what time after clinical infection. No commercially available assay currently exists that can determine adequate immunity to anthrax.

Children with active infection, either cutaneous or systemic, whose original exposure source was aerosolized spores, should complete initial antimicrobial treatment, then transition to oral PEP to prevent relapse from surviving *B anthracis* spores within the lung that may subsequently germinate. The du-

ration of antimicrobial therapy to prevent relapse is not well established. On the basis of incubation times of up to 43 days in humans and 58 days in animals exposed to aerosol challenge, a full 60-day course of an oral antimicrobial agent is recommended to complete treatment and prophylaxis.^{8,38,49} Therefore, once the treatment course for the active infection is completed, patients should continue with antimicrobial prophylaxis so that they receive antimicrobial treatment for a total of 60 days.

Naturally occurring *B anthracis* is very likely to be susceptible to penicillin; although genetic material that codes for the presence of a penicillinase is present, regulation of these genes may be deficient.^{50,51} Most strains are resistant to cephalosporins.⁵² Further, the naturally occurring strains that are penicillin-resistant remain susceptible to amoxicillin/clavulanate. Given the relative safety and tolerability of the penicillin-class agents in children, most pediatric experts prefer these antimicrobial agents for treatment and antimicrobial prophylaxis if pathogens are documented to be susceptible. Other antimicrobial classes, such as fluoroquinolones or tetracyclines, are likely to exhibit poorer tolerance and increased toxicity, especially during prolonged treatment.

A theoretical concern exists that the use of penicillins as single antimicrobial agents could induce β -lactam resistance, especially if the number of organisms present is high, as can occur with systemic disease. In addition, infection with multidrug-resistant *B anthracis*, including bioengineered strains, is a concern.⁵³ Therefore, public health authorities will monitor for the development of penicillin resistance on an ongoing basis even if strains are initially susceptible.

Given the potential severity of the disease, the fluoroquinolone class of

antimicrobial agents and doxycycline (a tetracycline) are acceptable alternatives if amoxicillin and penicillin are not options, either because *B anthracis* susceptibility is unknown to either of these drugs or because there are other contraindications for their use in treatment. Levofloxacin and ciprofloxacin have been prospectively studied in children, with adequate pharmacokinetic data for levofloxacin use in children older than 6 months and for ciprofloxacin use in children older than 1 year, but less robust data are available for younger infants or neonates. Studies have shown a small but statistically significant increase in arthralgia in children but no documented increase in long-term bone or joint toxicity.⁵⁴ Tetracycline-class antimicrobial agents, in general, are not recommended for first-line therapy of acute bacterial infection in children younger than 8 years (with the notable exceptions of rickettsial, *Ehrlichia*, and *Anaplasma* infections) because of deposition of these compounds in teeth and bones. Although prospective, controlled data are not available, limited retrospective data suggest that children who receive up to 5 standard treatment courses of doxycycline are not likely to have clinically detectable tooth staining.^{40,55}

Early diagnosis and initiation of combination antimicrobial therapy is considered essential for treatment of systemic *B anthracis* infection. Although it is always better to definitively identify the pathogen before treatment is administered, the rapid progression of anthrax may not support this approach. Samples for laboratory testing should be collected before treatment. The AAP and CDC Pediatric Anthrax Guidance Writing Group believe that severe systemic infection survival can improve with combination therapy on the basis of theoretical considerations of different mechanisms of antimicro-

bial activity, drug penetration characteristics, synergy with combinations, increased likelihood of effective drug activity in case of single or multidrug resistance, and decreased likelihood of emergence of resistance. Combinations recommended include both a bactericidal antimicrobial agent and a bacterial protein synthesis inhibitor (see the section "Treatment: Considerations for Combination Antimicrobial Therapy for Anthrax" later in this article). Compared with bacteriostatic agents, bactericidal antimicrobial agents are important for killing vegetative forms emerging from spores and are especially effective, in general, in clinical outcomes when used to treat bacterial meningitis.

The high morbidity and mortality observed with anthrax is attributable primarily to 2 exotoxins (lethal toxin and edema toxin) produced by *B anthracis*. Protein synthesis inhibitors, such as clindamycin, may decrease toxin production, as suggested with group A streptococcal toxic shock syndrome,^{56–58} which may provide an added benefit; however, this potential benefit has not been demonstrated in animal infection models or human cases of anthrax. Additional benefits may be provided by immunologic agents (such as immunoglobulin or antitoxin) that bind to the protective antigen of *B anthracis* to prevent attachment to host cells, neutralize toxin activity, or promote clearance of toxin complexes.

For children with overwhelming, severe disease who are not likely to survive, pediatric palliative care teams, if available, may be of value to consult with treating physicians or to provide support to the family and child.

Cutaneous Anthrax

Diagnosis

If cutaneous anthrax is suspected, swabs of vesicular fluid, eschar tissue,

or punch biopsy can be used to establish the diagnosis. Specimens should be submitted for Gram stain and culture. PCR assay and immunohistochemical staining of biopsies may be available through state or local public health laboratories or the CDC. The CDC provides a complete list of recommended specimens, including those listed previously and additionally blood for culture (or lethal toxin testing or antiprotective antigen serology) and swabs from beneath the eschar (www.cdc.gov/anthrax/labs/recommended_specimen.html).

Treatment

Localized or uncomplicated cutaneous anthrax is a less-severe disease. Historically, naturally acquired infection has been successfully treated in 7 to 10 days with a single oral antimicrobial agent, such as either amoxicillin for susceptible strains or ciprofloxacin, before susceptibility testing or for penicillin-resistant strains (Appendix 2). Many patients with uncomplicated cutaneous anthrax can be treated as outpatients. However, hospitalization is necessary for patients with symptoms or signs of systemic involvement, particularly those with lesions of the head or neck that may rapidly progress to include edema that can compromise the airway.

The use of surgical procedures, such as incision, in the treatment of cutaneous anthrax is usually not required, because the lesions do not contain pus. Use of surgical procedures may be associated with poor outcomes.^{59,60} Treatment should focus instead on early initiation of antimicrobial agents and on local wound care. Exceptions to the general surgical contraindication include interventions to relieve airway obstruction or compartment syndrome, particularly for large or circumferential lesions of the extremities.^{61,62}

As a child is started on therapy, cutaneous anthrax can evolve into disease

with systemic involvement, requiring the use of intravenous combination therapy (Appendices 3 and 4). Children who present with cutaneous anthrax during a biological weapon–related event also may have inhaled spores; after treatment, they should receive additional antimicrobial therapy to complete a total of 60 days of therapy.

Inhalation Anthrax

Diagnosis

For suspected inhalation anthrax, a chest radiograph should be performed to assess for a widened mediastinum, pleural effusions, and/or pulmonary infiltrates. In a review of 82 cases of inhalation anthrax, abnormal radiologic findings were reported in all 26 patients for whom chest radiographs were obtained; findings included pleural effusion in 69% of these patients and widened mediastinum in 54%.²⁵ Radiologic findings in children have been reported in only 2 children with inhalation anthrax, but typical findings, such as pleural effusions and widened mediastinum, were reported in both.²⁷ If there is strong suspicion of anthrax on the basis of exposure history and a questionable chest radiograph, a computed tomography (CT) scan of the chest may provide additional information to support the presumptive diagnosis.⁶³ However, during a biological weapon event, access to diagnostic radiology services may become difficult; therefore, assessing risk of anthrax exposure or clinical signs may be used initially to determine suspicion of inhalation anthrax and guide management accordingly.

Extrapolating from adult data, inhalation anthrax can have a biphasic presentation with initial improvement, followed by precipitous hemodynamic deterioration.^{7,24} Because of this potential for sudden decompensation, patients who are hospitalized and treated for suspected anthrax should have

careful hemodynamic monitoring, including continuous pulse oximetry and continuous cardiorespiratory monitoring for at least 24 to 48 hours, even if initial findings are reassuring.

Treatment: General Supportive Care and Ventilator Management

A review of inhalation anthrax cases from 1990 through 2005 showed a significant association between pleural fluid drainage and survival.²⁵ High concentrations of lethal toxin have been detected in pleural fluid and ascites; therefore, prompt and continuous drainage by chest and/or peritoneal tube is critical. Ultrasonography of the chest may be a useful way to detect and monitor pleural fluid. Thoracotomy may be required for loculated or gelatinous effusions.

Patients with anthrax may require mechanical ventilation because of respiratory distress or imminent shock. In addition, some patients with anthrax may require respiratory support for severe edema that may occur with cutaneous lesions involving the head, neck, oropharynx, or thorax. Intubation or tracheostomy may be required to maintain the airway. Although there are significant differences between the pathophysiology of anthrax and respiratory distress syndrome, standard principles of ventilator management apply in both situations. Standard pediatric sepsis guidelines for fluids, vasopressors, blood products, and hemodynamic monitoring should also be followed (Appendix 7).

Treatment: Considerations for Combination Antimicrobial Therapy for Anthrax

The antimicrobial treatment of inhalation anthrax should follow the guidance for severe, systemic anthrax, both for those children for whom a lumbar puncture can be performed and meningitis is unlikely (Appendix 3)

and those in whom meningitis cannot be ruled out (Appendix 4). Patients presenting with signs or symptoms suggestive of pneumonia or systemic anthrax should be started on combination antimicrobial therapy as soon as possible while awaiting results of confirmatory tests. Before recognition of a *B anthracis* biological weapon event, the differential diagnosis for a severe systemic bacterial infection in a child usually warranted broad-spectrum antimicrobial coverage; however, cephalosporin therapy, often used empirically for community-acquired infections, is not active against *B anthracis*. Once the diagnosis of anthrax is confirmed, or in the midst of a biological weapon exposure, individuals presenting with illness consistent with anthrax would warrant therapy targeted more specifically to *B anthracis*. Given the unique drug disposition in preterm and term neonates during the first month of life, specific doses for this age group have been provided in Appendix 6.

Antimicrobial agents must penetrate into appropriate tissue sites, particularly into the CNS for children with systemic disease, especially if meningitis cannot be excluded. Meningitis and hemorrhagic parenchymal brain infection resulting from hematogenous spread must be considered in all children presenting with severe systemic anthrax.

For therapy of severe systemic anthrax in which anthrax meningitis is a consideration, treatment regimens for meningitis that include 2 bactericidal antimicrobial agents and 1 protein-synthesis inhibitor should be followed (Appendix 4). Before susceptibility testing, and for penicillin-resistant strains, ciprofloxacin remains the preferred bactericidal antimicrobial agent, in addition to meropenem. If those antimicrobial agents are not available, levofloxacin or imipenem should be

used. For susceptible strains, penicillin G (intravenous) or ampicillin are recommended, in addition to ciprofloxacin, as first-line antimicrobial agents, avoiding the unnecessary broad-spectrum activity of meropenem. Linezolid is the preferred protein-synthesis inhibitor for CNS infections on the basis of tissue penetration characteristics (Appendix 4). However, if meningitis has been ruled out by CSF examination and/or imaging, treatment may be reduced to a combination of 2, rather than 3, antimicrobial agents with activity against *B anthracis*: 1 with bactericidal activity and 1 protein synthesis inhibitor (Appendix 3). If it is not possible to examine the CSF or perform imaging studies, but the clinical examination 2 to 3 days into therapy suggests that meningitis was not present by a normal neurologic examination, initial triple antimicrobial therapy can be stepped down to dual antimicrobial therapy (Appendix 3).

When meningitis is not a concern, clindamycin should be used as a protein synthesis inhibitor, rather than linezolid, primarily on the basis of concerns for safety. Doxycycline is an alternative protein synthesis inhibitor choice for treatment in all pediatric age groups for non-CNS anthrax. Rifampin is an additional option with the potential to provide synergistic antibacterial activity when used in combination with other agents if the preferred antimicrobial agents are not available or not tolerated.

After completing initial combination therapy for severe disease, all children with systemic illness, excluding meningitis, may switch to oral follow-up therapy (assuming that children can tolerate oral therapy and families are adherent to providing therapy) to complete a 14-day or longer treatment course (as dictated by clinical improvement), followed by prophylaxis,

totaling 60 days (Appendix 5). Although data on the efficacy of oral follow-up therapy after short-course parenteral therapy of systemic anthrax are lacking, the recommended antimicrobial agents all have good oral absorption characteristics and have been used as oral therapy of other infections in children. Children who appear to be well, with no ongoing signs or symptoms of active infection, may be transitioned from parenteral therapy to monotherapy for the remainder of their 14 days of treatment. Those for whom there is some degree of concern about persistent deep infection or who are slower to recover may be transitioned to oral therapy that includes both a bactericidal antimicrobial agent and a protein synthesis inhibitor for the remainder of their 14 days of treatment (Appendix 5). Ciprofloxacin is the preferred antimicrobial agent for penicillin-resistant strains. Doxycycline, clindamycin, and levofloxacin should all provide adequate single-drug therapy. For penicillin-susceptible strains, amoxicillin is preferred therapy, although treating physicians should be aware of theoretical concerns for emergence of penicillin-resistance during monotherapy and be alert to the possibility of clinical deterioration as a result of resistance. In these situations, cultures should be obtained, if possible, to determine whether the organism has become resistant to amoxicillin, and the class of prescribed antimicrobial agent should be changed to those active against penicillin-resistant strains, as noted previously.

Gastrointestinal Anthrax

Diagnosis

When gastrointestinal anthrax is suspected, blood cultures should be performed before starting antimicrobial therapy, and culture and PCR of ascites fluid, stool or rectal swabs, or oropharyngeal lesions, if present, are

recommended. Please see www.cdc.gov/anthrax/labs/recommended_specimen.html for all recommended diagnostic specimens for gastrointestinal anthrax.

Treatment

Antimicrobial therapy should follow the same guidance as that for systemic inhalation anthrax: 3 antimicrobial agents for children with possible or documented associated meningitis (Appendix 4) and 2 for those in whom meningitis can be excluded (Appendix 3).

Anthrax Meningoencephalitis

Diagnosis

Evaluation of CSF in the stable patient can provide laboratory evidence of meningoencephalitis as well as microbiologic confirmation of the etiology. For children too unstable to undergo lumbar puncture, CNS imaging by CT with contrast or magnetic resonance imaging with contrast should be able to document both meningeal enhancement characteristics of infection in addition to identification of hemorrhagic parenchymal lesions characteristic of anthrax meningoencephalitis. If imaging is not possible in the child with altered mental status or seizure activity, then clinical examination findings suggestive of meningitis (such as nuchal rigidity) should be presumed to be caused by meningoencephalitis and treated accordingly. If meningitis cannot be ruled out by laboratory, imaging, or physical examination, the child should be treated as though meningoencephalitis is present.

Treatment

Patients with confirmed or presumptive anthrax meningoencephalitis should be treated with 3 intravenous antimicrobial agents as noted previously in "Treatment: Considerations for Combination Antimicrobial Therapy for

Anthrax.” All antimicrobial agents used should have good CNS penetration, at least 2 should have bactericidal activity, and at least 1 should inhibit protein synthesis (Appendix 4). It is assumed that during a biological weapon event, limited availability of some antimicrobial agents will exist; therefore, many alternative antimicrobial agents also have been listed, some lacking documented evidence of efficacy in CNS infections.

Intravenous ciprofloxacin is recommended as the primary bactericidal antimicrobial agent for meningoen- cephalitis on the basis of efficacy in nonhuman primate infection models and use in anthrax cases since 2001, unless ciprofloxacin use is contra- indicated. Levofloxacin and moxi- floxacin are considered equivalent alternatives to ciprofloxacin, although less experience is available with these antimicrobial agents in children. These fluoroquinolone antimicrobial agents have been shown to have adequate CNS penetration.^{64,65} No re- ports exist to document naturally occurring fluoroquinolone-resistant strains. However, in vitro resistance can be induced, which has implica- tions for bioengineered strains.

An antimicrobial agent from the β -lactam class with activity against *B anthracis* is recommended in combi- nation with fluoroquinolones to treat systemic anthrax cases in which meningitis may be present. If antimi- crobial susceptibilities are unknown or if the *B anthracis* strain is resistant to penicillin, meropenem is the pre- ferred antimicrobial agent, because carbapenems are stable to the β -lactamases of *B anthracis*, and meropenem is approved by the FDA for use in pediatric meningitis; how- ever, meningoen- cephalitis caused by *B anthracis* has not been prospectively studied. If meropenem is not avail- able, imipenem/cilastatin is considered

equivalent in antibacterial activity. How- ever, imipenem/cilastatin is associated with an increased risk of seizures when used in the treatment of menin- gitis, presumably by lowering the sei- zure threshold,^{66,67} and should be used with caution in patients with suspected meningitis. Pharmacokinetic data are available for use in children. Limited data are available for doripenem pharmacokinetics or clinical efficacy in children, but if meropenem and imi- penem are not available, data from experimental animal models of men- ingitis suggest similar efficacy.⁶⁸ If the isolated *B anthracis* strain is suscep- tible to penicillin, penicillin G or ampi- cillin are preferred antimicrobial agents given their long history of use, safety profile, and narrower antimi- crobial spectrum. However, as noted earlier, most strains contain a β -lac- tamase that is usually not associated with clinically relevant resistance but represents a potential for development of resistance to penicillin or ampicillin while on therapy. Emergence of re- sistance to penicillin would require treatment with meropenem or another carbapenem (Appendix 4).

Vancomycin has demonstrated in vitro activity against naturally occurring strains but has limited human clinical treatment data in anthrax. Vancomy- cin is bactericidal, achieves adequate CNS concentrations, has been used extensively in pediatric meningitis, and may be used as an alternative antimicrobial agent if β -lactam anti- microbial agents are not available (Appendix 4).⁶⁹

At least 1 antimicrobial agent that inhibits protein synthesis is recom- mended for inclusion in the antimi- crobial regimen to reduce production of exotoxins. Linezolid is recommended as the first-line protein synthesis in- hibitor. It is recommended over clin- damycin when meningitis is suspected or cannot be excluded, as it is likely

to provide better CNS penetrance, although prospective, controlled data on the treatment of CNS infections with either antimicrobial agent do not ex- ist.^{70–73} Linezolid toxicity must be taken into consideration. Peripheral and optic neuropathy have been re- ported in both adults and children receiving prolonged courses of line- zolid.^{74–76} Myelosuppression is a po- tential adverse effect more commonly seen when linezolid is used for more than 14 days, but it is reversible and can be managed with marrow-stimulating agents.⁷⁷ Linezolid should be used with caution in patients with preexisting myelosuppression. If patients have con- traindications to linezolid use or it is not available, clindamycin is an acceptable alternative. Rifampin, although not a protein synthesis inhibitor, has been widely used for antibacterial synergy with a primary drug and could be used in this capacity if neither linezolid nor clindamycin are available.

Chloramphenicol historically has been used to successfully treat anthrax⁷⁸; it is a protein synthesis inhibitor with excellent CNS penetration. The in- travenous form is not widely available in the United States, and the oral formulation is no longer available. In- travenous chloramphenicol would be an acceptable alternative if linezolid, clindamycin, and rifampin are not available for use. Doxycycline should not be used as first-line therapy if meningitis is suspected because of variable CNS penetration compared with fluoroquinolones and β -lactams, but it may be effective if other pre- ferred antimicrobial agents are not available or are not tolerated.

Duration of initial intravenous combi- nation therapy is determined by meningitis risk and clinical response to treatment. With mortality rates for meningoen- cephalitis approaching 100%, no prospective data exist on which to base recommendations for an effective

treatment duration.⁶⁹ For children with meningoencephalitis or in children for whom meningitis cannot be ruled out, combination therapy is recommended for a minimum of 2 weeks, depending on the severity of disease and presence of brain parenchymal hemorrhagic lesions. Intravenous therapy should continue until the patient is clinically stable, with all clinical signs and symptoms and laboratory and imaging data documenting resolution of inflammation, even if required for 3 to 6 weeks. As with other forms of anthrax secondary to a biological weapon exposure, ongoing oral PEP therapy should continue until antimicrobial therapy has been administered for a total of 60 days.

Use of Corticosteroids

There are limited data to guide use of corticosteroids in anthrax. Clinicians should maintain a high index of suspicion for adrenal failure and perform adrenal hormone replacement therapy with dosing appropriate for stressed patients if adrenal failure is suspected on the basis of history or pressor-refractory hypotension. Although there are no randomized trials of corticosteroid use in human anthrax, adjunctive corticosteroids in anthrax may be considered for management of severe edema or meningoencephalitis. In a systematic review of anthrax meningitis by Sejvar et al,⁶⁹ survival was slightly increased among patients with meningoencephalitis who received steroids compared with those who did not. Several small observational studies of anthrax involving the head and neck appeared to favor their use in this setting. Although corticosteroid doses have not been studied prospectively in anthrax, doses previously used in pediatric bacterial meningitis (dexamethasone 0.6 mg/kg per day, in divided doses every 6 hours for 4 days) should be appropriate.⁷⁹

Antitoxins

Human data from the pre-antimicrobial era suggest that nonhuman anthrax antiserum reduced the mortality rate for cutaneous anthrax and that antiserum might be beneficial in inhalation anthrax. Two antitoxin products are in the Strategic National Stockpile: raxibacumab (a humanized monoclonal antibody) and Anthrax Immune Globulin (AIG [a polyclonal human immunoglobulin]). Raxibacumab is approved by the FDA for use in adults and children for the treatment or prevention of anthrax. On the basis of animal studies, pediatric population pharmacokinetic modeling was performed by the manufacturer, and proposed weight-based doses for children are provided on the package label (www.accessdata.fda.gov/drugsatfda_docs/label/2012/125349s000lbl.pdf). AIG is not currently approved by the FDA and will need to be administered under an Investigational New Drug application or Emergency Use Authorization during a mass exposure event.

Suggested doses of antitoxin preparations for children that reflect current knowledge of the product will accompany raxibacumab and AIG when these products are shipped to points of dispensing located in proximity to the anthrax exposure site. Both products inhibit *B anthracis* protective antigen binding to the anthrax toxin receptors on human cells and subsequent translocation of the 2 primary toxins into cells.⁸⁰

In animal studies, both raxibacumab and AIG have been shown to be effective for treatment of inhalation anthrax when administered without antimicrobial agents.¹ Both have been studied in animals as adjunctive therapy with antimicrobial agents when treatment is delayed and appear to provide additional survival benefit. Both products have been studied in adult volunteers for pharmacokinetics and safety. AIG

has been administered to 3 adults with inhalation anthrax, 1 with gastrointestinal anthrax, and 15 with injection anthrax. Raxibacumab has been used in animal models of inhalation anthrax but has not yet been used to treat human disease. The products appear to be safe and well-tolerated. Headache, sore throat, and nausea were the most commonly reported adverse effects with AIG, and rash occurred in a small number of recipients of raxibacumab. Pretreatment with diphenhydramine is recommended for patients who will be receiving raxibacumab (www.accessdata.fda.gov/drugsatfda_docs/label/2012/125349s000lbl.pdf).

The AAP and CDC recommend the use of antitoxin in addition to systemic antimicrobial agents for all patients with highly suspect (eg, child exposed during a bioterror event, with systemic signs and symptoms compatible with inhalation, gastrointestinal, or meningeal anthrax) or confirmed systemic anthrax. Antimicrobial agents alone can be effective if initiated early in the course of disease. However, given the high mortality rate of systemic anthrax and the apparently low risk of antitoxins, the potential benefits appear to greatly outweigh the risks. Data on the optimal timing are lacking, but most experts favor early administration. During a biological weapon event in which the number of patients with anthrax exceeds available antitoxin and ill patients may overwhelm the health care system, antitoxin should be reserved for patients most likely to benefit from it, including (1) noncritically ill, nonmoribund children with confirmed systemic anthrax in relatively stable clinical condition, and (2) critically ill nonmoribund children who may have progressive disease with dysfunction in 1 or more organ systems. In such an event, antitoxin should be added to combination antimicrobial therapy. Insufficient data are

available to recommend one antitoxin product routinely over the other. During an event, recommendations on dosing will be provided with the antitoxin products.

CONSIDERATIONS FOR BREASTFEEDING INFANTS

Unless breastfeeding mothers have untreated cutaneous lesions on their breasts, mothers should initiate and continue breastfeeding, if able, after exposure to *B anthracis* spores when they are undergoing treatment of disease and when they are receiving vaccine and antimicrobial agents for PEP. Cutaneous lesions are not considered contagious after 24 to 48 hours of effective antimicrobial therapy. Given the various considerations of the potential lethality of anthrax in both the infant and mother, antimicrobial efficacy, infant safety, and the well-known benefits of breastfeeding, the selection of antimicrobial agents and PEP for breastfeeding mothers should not be modified from those for the general adult population. More specific recommendations for compatibility of certain antimicrobial agents and breastfeeding can be found in Appendix 8.

The decision with respect to PEP therapy for breastfeeding mothers should be independent of that for the infant,⁸¹ including the long-term use of fluoroquinolones or doxycycline. The safety of 60 days of infant exposure to maternal antimicrobial agents through human milk is largely unknown but should not in any way affect the need to appropriately treat the mother.⁸² Breastfeeding infants should receive prophylaxis as recommended, regardless of the prophylaxis status of the mother. Additional guidance for pregnant and lactating mothers may be found in a recent review from the CDC by Meaney-Delman and colleagues.⁸³

CONCLUSIONS

The use of *B anthracis* as a biological weapon is considered by the US government to be a potential national security threat. Therefore, the clinical and public health communities must be prepared to dispense prophylactic antimicrobial agents, antitoxin agents, and vaccines¹¹⁵ to prevent disease and treat children who develop infection. To optimally manage children during an anthrax bioterror event, ready access to information from public health officials by health care providers and information communicated back to public health officials from health care providers is critical. Clear recommendations and consistent messaging to the public from both public health officials and health care providers will be extremely important.

Recommendations and key considerations (main points) in a mass *B anthracis* exposure scenario include the following:

Management of Exposed but Asymptomatic Children

1. Within 48 hours of exposure to *B anthracis* spores, public health authorities plan to provide a 10-day course of antimicrobial prophylaxis to the local population likely to have been exposed, contingent on available resources.
2. Within 10 days of exposure, public health authorities plan to further define those who have had a clear and significant exposure and will require an additional 50 days of antimicrobial PEP as well as the 3-dose AVA series under an Investigational New Drug application. For children younger than 6 weeks (who are not candidates for AVA), antimicrobial prophylaxis should begin immediately, but the vaccine series should be delayed until the child reaches 6 weeks of age.

3. A local adverse event to a prior dose of AVA is not a contraindication to receiving additional doses, although the subsequent dose should be administered at an alternate site and closely monitored.
4. Although not strictly contraindicated, AVA should not be coadministered with routine childhood vaccinations during an anthrax event.

Management of Disease

5. Anthrax may occur in different clinical forms, any of which may progress to systemic disease. Treatment will vary by clinical manifestation.
6. Cutaneous anthrax without systemic involvement that occurs in the context of an anthrax bioterror event should be treated with a single oral antimicrobial agent.
7. Inhalation, gastrointestinal, or other systemic disease without meningoencephalitis should be treated with at least 2 intravenous antimicrobial agents: a bactericidal agent and a protein synthesis inhibitor.
8. Systemic disease with possible or confirmed meningoencephalitis should be treated with 3 intravenous antimicrobial agents with adequate CNS penetration, including 2 bactericidal agents and a protein synthesis inhibitor.
9. Antitoxin (either AIG or raxibacumab) is recommended for children with anthrax systemic disease.
10. Corticosteroid adjunctive therapy may be considered in the management of children with severe cerebral edema or meningoencephalitis.
11. Once therapy has been completed for any form of systemic or cutaneous anthrax infection in children involved in an aerosol *B anthracis* dispersal event, appropriate oral antimicrobial agents

should be provided to complete a full 60 days of therapy.

12. Breastfeeding should continue for infants of mothers who require antimicrobial treatment or prophylaxis or anthrax vaccine.

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APPENDIX 1 Postexposure Prophylaxis for *B anthracis* (for Children 1 Month of Age and Older)**1. For penicillin-resistant strains or prior to susceptibility testing*****Ciprofloxacin*, 30 mg/kg/day, by mouth (PO), divided every 12 h (not to exceed 500 mg/dose)**

OR

***Doxycycline*,^a <45 kg: 4.4 mg/kg/day, PO, divided every 12 h (not to exceed 100 mg/dose) >45 kg: 100 mg/dose, PO, given every 12 h**

OR

***Clindamycin*,^b 30 mg/kg/day, PO, divided every 8 h (not to exceed 900 mg/dose)**

OR

***Levofloxacin*,^c <50 kg: 16 mg/kg/day, PO, divided every 12 h (not to exceed 250 mg/dose) >50 kg: 500 mg, PO, given every 24 h**

OR

2. For penicillin-susceptible strains^{b,d}***Amoxicillin*, 75 mg/kg/day, PO, divided every 8 h (not to exceed 1 g/dose)**

OR

Penicillin VK*, 50–75 mg/kg/day, PO, divided every 6 to 8 h*Duration of Therapy: 60 days after exposure**

Bold font: preferred antimicrobial agent (when 2 bolded antimicrobial agents are present, both are considered equivalent in overall safety and efficacy).

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot take first-line therapy or if first-line therapy is unavailable.

Doses are provided for children with normal renal and hepatic function. Doses may vary for those with some degree of organ failure.

Italicized font: indicates FDA approval for the indication in the pediatric population.

^a A single 14-day course of doxycycline is not routinely associated with tooth staining, but some degree of staining is likely for a prolonged treatment course of up to 60 days.^b On the basis of in vitro susceptibility data.^c Safety data for levofloxacin in the pediatric population are limited to 14 days for duration therapy.^d Be aware of the possibility of emergence of penicillin-resistance during monotherapy with amoxicillin or penicillin.**APPENDIX 2** Treatment of Cutaneous Anthrax Without Systemic Involvement (for Children 1 Month of Age and Older)**1. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown*****Ciprofloxacin*, 30 mg/kg/day, by mouth (PO), divided every 12 h (not to exceed 500 mg/dose)**

OR

***Doxycycline*,^a <45 kg: 4.4 mg/kg/day, PO, divided every 12 h (not to exceed 100 mg/dose) ≥45 kg: 100 mg/dose, PO, given every 12 h**

OR

***Clindamycin*,^b 30 mg/kg/day, PO, divided every 8 h (not to exceed 600 mg/dose)**

OR

***Levofloxacin* <50 kg: 16 mg/kg/day, PO, divided every 12 h (not to exceed 250 mg/dose) >50 kg: 500 mg, PO, given every 24 h**

OR

2. Alternatives for penicillin-susceptible strains^c***Amoxicillin*, 75 mg/kg/day, PO, divided every 8 h (not to exceed 1 g/dose)**

OR

Penicillin VK*, 50–75 mg/kg/day, PO, divided every 6 to 8 h*Duration of therapy:****For naturally acquired infection: 7–10 days.****For a biological weapon-related event: will require additional prophylaxis for inhaled spores, to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 1, Postexposure Prophylaxis).**

Bold font: preferred antimicrobial agent.

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot take first-line therapy or if first-line therapy is unavailable.

Doses are provided for children with normal renal and hepatic function. Doses may vary for those with some degree of organ failure.

Italicized font: indicates FDA approval for the indication in the pediatric population.

^a A single 10- to 14-day course of doxycycline is not routinely associated with tooth staining.^b On the basis of in vitro susceptibility data.^c Be aware of the possibility of emergence of penicillin-resistance during monotherapy with amoxicillin or penicillin.

APPENDIX 3 Combination Therapy for Systemic Anthrax When Meningitis Can Be Ruled Out (for Children 1 Month of Age and Older)**1. A bactericidal antimicrobial****a. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown****Ciprofloxacin, 30 mg/kg/day, intravenously (IV), divided every 8 h (not to exceed 400 mg/dose)**

OR

Meropenem, 60 mg/kg/day, IV, divided every 8 h (not to exceed 2 g/dose)

OR

Levofloxacin <50 kg: 20 mg/kg/day, IV, divided every 12 h (not to exceed 250 mg/dose) >50 kg: 500 mg, IV, given every 24 h

OR

Imipenem/cilastatin,^a 100 mg/kg/day, IV, divided every 6 h (not to exceed 1 g/dose)

OR

Vancomycin, 60 mg/kg/day, IV, divided every 8 h (follow serum concentrations)

b. Alternatives for penicillin-susceptible strains**Penicillin G, 400 000 U/kg/day, IV, divided every 4 h (not to exceed 4 MU/dose)**

OR

Ampicillin, 200 mg/kg/day, IV, divided every 6 h (not to exceed 3 g/dose)

PLUS**2. A Protein Synthesis Inhibitor****Clindamycin, 40 mg/kg/day, IV, divided every 8 h (not to exceed 900 mg/dose)**

OR

Linezolid^b (non-CNS infection dose): <12 y old: 30 mg/kg/day, IV, divided every 8 h ≥12 y old: 30 mg/kg/day, IV, divided every 12 h (not to exceed 600 mg/dose)

OR

Doxycycline^c <45 kg: 4.4 mg/kg/day, IV, loading dose (not to exceed 200 mg); ≥45 kg: 200 mg, IV, loading dose then <45 kg: 4.4 mg/kg/day, IV, divided every 12 h (not to exceed 100 mg/dose); ≥45 kg: 100 mg, IV, given every 12 h

OR

Rifampin,^d 20 mg/kg/day, IV, divided every 12 h (not to exceed 300 mg/dose)**Duration of therapy: For 14 days or longer until clinical criteria for stability are met (see text). Will require prophylaxis to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 1).**

Systemic anthrax includes inhalation anthrax; injection, gastrointestinal, or cutaneous anthrax with systemic involvement, extensive edema, or lesions of the head or neck.

Children with altered mental status, signs of meningeal inflammation, or focal neurologic deficits should be considered to have CNS infection if CSF examination is not possible. A normal CSF may not completely exclude deep brain hemorrhage/abscess. See Appendix 4 for therapy of CNS infection.

Bold font: preferred antimicrobial agent.

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot tolerate first-line therapy or if first-line therapy is unavailable.

Doses are provided for children with normal renal and hepatic function. Doses may vary for those with some degree of organ failure.

^a Increased risk of seizures associated with imipenem/cilastatin therapy.^b Linezolid should be used with caution in patients with thrombocytopenia, as it may exacerbate it. Linezolid use for >14 days carries additional hematopoietic toxicity.^c A single 14-day course of doxycycline is not routinely associated with tooth staining.^d Rifampin is not a protein synthesis inhibitor; it may also be used in combination therapy based on in vitro synergy.

APPENDIX 4 Triple Therapy for Systemic Anthrax (Anthrax Meningitis or Disseminated Infection and Meningitis Cannot Be Ruled Out) for Children 1 Month of Age and Older

1. A bactericidal antimicrobial (fluoroquinolone)

Ciprofloxacin, 30 mg/kg/day, intravenously (IV), divided every 8 h (not to exceed 400 mg/dose)^a

OR

Levofloxacin <50 kg: 16 mg/kg/day, IV, divided every 12 h (not to exceed 250 mg/dose); >50 kg: 500 mg, IV, every 24 h

OR

Moxifloxacin 3 mo to <2 y: 12 mg/kg/day, IV, divided every 12 h (not to exceed 200 mg/dose)

2–5 y: 10 mg/kg/day, IV, divided every 12 h (not to exceed 200 mg/dose)

6–11 y: 8 mg/kg/day, IV, divided every 12 h (not to exceed 200 mg/dose)

12–17 y, ≥45 kg body weight: 400 mg, IV, once daily

12–17 y, <45 kg body weight: 8 mg/kg/day, IV, divided every 12 h (not to exceed 200 mg/dose)

PLUS

2. A bactericidal antimicrobial (β-lactam or glycopeptide)

a. For all strains, regardless of penicillin susceptibility testing or if susceptibility is unknown

Meropenem, 120 mg/kg/day, IV, divided every 8 h (not to exceed 2 g/dose)

OR

Imipenem/cilastatin,^b 100 mg/kg/day, IV, divided every 6 h (not to exceed 1 g/dose)

OR

Doripenem,^c 120 mg/kg/day, IV, divided every 8 h (not to exceed 1 g/dose)

OR

Vancomycin, 60 mg/kg/day, IV, divided every 8 h

b. Alternatives for penicillin-susceptible strains

Penicillin G, 400 000 U/kg/day, IV, divided every 4 h (not to exceed 4 MU/dose)

OR

Ampicillin, 400 mg/kg/day, IV, divided every 6 h (not to exceed 3 g/dose)

PLUS

3. A Protein Synthesis Inhibitor

Linezolid^d: <12 y old: 30 mg/kg/day, IV, divided every 8 h ≥12 y old: 30 mg/kg/day, IV, divided every 12 h (not to exceed 600 mg/dose)

OR

Clindamycin, 40 mg/kg/day, IV, divided every 8 h (not to exceed 900 mg/dose)

OR

Rifampin,^e 20 mg/kg/day, IV, divided every 12 h (not to exceed 300 mg/dose)

OR

Chloramphenicol,^f 100 mg/kg/day, IV, divided every 6 h

Duration of therapy: for 2–3 wk or greater, until clinical criteria for stability are met (see text). Will require prophylaxis to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 1).

Systemic anthrax includes anthrax meningitis; inhalation anthrax; or injection, gastrointestinal, and cutaneous anthrax with systemic involvement, extensive edema, or lesions of the head or neck.

Children with altered mental status, signs of meningeal inflammation, or focal neurologic deficits should be considered to have CNS infection if CSF examination is not possible. Normal CSF may not completely exclude deep brain hemorrhage/abscess.

Bold font: preferred antimicrobial agent.

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot tolerate first-line therapy or if first-line therapy is unavailable.

Doses are provided for children with normal renal and hepatic function. Doses may vary for those with some degree of organ failure.

^a A 400-mg dose of ciprofloxacin, IV, provides an equivalent exposure to that of a 500-mg ciprofloxacin oral tablet.

^b Increased risk of seizures associated with imipenem/cilastatin therapy.

^c Doripenem is approved in Japan at this dose for the treatment of community-acquired bacterial meningitis.

^d Linezolid should be used with caution in patients with thrombocytopenia, as it may exacerbate it. Linezolid use for >14 days carries additional hematopoietic toxicity.

^e Rifampin is not a protein synthesis inhibitor; it may also be used in combination therapy based on in vitro synergy for some strains of staphylococci. Not evaluated for *B anthracis*.

^f Should be used only if other options are not available, because of toxicity concerns.

APPENDIX 5 Oral Follow-up Combination Therapy for Severe Anthrax (for Children 1 Month of Age and Older)**1. A bactericidal antimicrobial****a. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown****Ciprofloxacin, 30 mg/kg/day, by mouth (PO), divided every 12 h (not to exceed 500 mg/dose)**

OR

Levofloxacin <50 kg: 16 mg/kg/day, PO, divided every 12 h (not to exceed 250 mg/dose) ≥50 kg: 500 mg, PO, given every 24 h

OR

b. Alternatives for penicillin-susceptible strains**Amoxicillin, 75 mg/kg/day, PO, divided every 8 h (not to exceed 1 g/dose)**

OR

Penicillin VK, 50–75 mg/kg/day, PO, divided every 6 to 8 h

PLUS**2. A protein synthesis inhibitor****Clindamycin^a 30 mg/kg/day, PO, divided every 8 h (not to exceed 600 mg/dose)**

OR

Doxycycline^b <45 kg: 4.4 mg/kg/day, PO, divided every 12 h (not exceed 100 mg/dose) ≥45 kg: 100 mg, PO, given every 12 h

OR

Linezolid^c (non-CNS infection dose):

<12 y old: 30 mg/kg/day, PO, divided every 8 h

≥12 y old: 30 mg/kg/day, PO, divided every 12 h

(not to exceed 600 mg/dose)

Duration of therapy: to complete a treatment course of 14 days or greater. May require prophylaxis to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 1).

Severe anthrax includes inhalation anthrax; injection, gastrointestinal, or cutaneous anthrax with systemic involvement, extensive edema, or lesions of the head or neck.

Bold font: preferred antimicrobial agent.

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot take first-line therapy or if first-line therapy is unavailable.

Doses are provided for children with normal renal and hepatic function. Doses may vary for those with some degree of organ failure.

^a Based on in vitro susceptibility data rather than studies of clinical efficacy.^b A single 14-day course of doxycycline is not routinely associated with tooth staining.^c Linezolid should be used with caution in patients with thrombocytopenia, as it may exacerbate it. Linezolid use for >14 days carries additional hematopoietic toxicity.

THESE ANTIMICROBIALS AND DOSAGES HAVE NOT BEEN REVIEWED OR APPROVED BY THE FDA FOR USE IN NEWBORN INFANTS, UNLESS SPECIFICALLY NOTED. THESE DOSES ARE PROVIDED ONLY AS GUIDANCE DURING AN EMERGENCY BIOLOGICAL WEAPON EVENT, ON THE BASIS OF AVAILABLE LITERATURE OR EXTRAPOLATION FROM PHARMACOKINETIC DATA FROM OLDER CHILDREN, WITH KNOWLEDGE OF MATURATION OF NEONATAL CLEARANCE MECHANISMS.

Dosing guidance for anthrax in newborn infants has not been proposed earlier because of the paucity of pharmacologic data describing kinetics, safety, and efficacy and the broad range of developmental changes that will affect therapy in this immature population. This guidance accommodates not only term newborn infants but also neonates who may be born at 32 wk postmenstrual age (PMA). For neonates of earlier gestational age, please consult with a neonatologist, pharmacologist, or infectious diseases physician for appropriate dosing. Doses are provided for newborns with developmentally appropriate renal and hepatic function. Doses may vary for those with some degree of organ failure.

By convention, the neonatal period ends 28 d (4 wk) after birth, but at 4 wk of age, the physiologic maturity of a preterm infant lags significantly behind a term infant. Preterm infants continue to undergo developmental changes through 44 wk PMA that affect pharmacokinetics, with maturation of mechanisms of renal elimination and hepatic enzymatic drug inactivation that occur at different rates for different antimicrobial agents, some closely linked to PMA or chronologic age, but most demonstrate aspects of both. Hence, we provide guidance for all newborn infants through 44 wk PMA while recognizing that many physiologic processes mature during this developmental period and that new dosing recommendations are likely to follow as additional data become available. Should these medications be required for treatment or prophylaxis, it will be especially important to plan prospectively to monitor serum/plasma concentrations in a systematic fashion to acquire good data that relate dose of drug to concentration, efficacy, and occurrence of adverse effects.

Antimicrobial-related adverse effects are always possible; however, the benefit of antimicrobial therapy for life-threatening infection justifies assuming greater risk during therapy. In general, the frequency and severity of adverse events seem to be less, rather than more, in neonates.

Duration of therapy: For ≥ 2 –3 wk, until clinical criteria for stability are met (see text). Will require prophylaxis to complete an antibiotic course of up to 60 days from onset of illness (see Appendix 6E).

Term Newborn Infant

1–4 wk of Age

**30 mg/kg/day,
divided q12h**

10 mg/kg/day,
q24h

90 mg/kg/day,
divided q8h

75 mg/kg/day,
divided q8h

30 mg/kg/day,
divided q8h

400 000 Units/
kg/day,
divided q6h

200 mg/kg/day,
divided q6h

30 mg/kg/day,
divided q8h

20 mg/kg/day,
divided q6h

OR

APPENDIX 6 Continued

Rifampin ^f 103–105	10 mg/kg/day, divided q12h	10 mg/kg/day, divided q12h	10 mg/kg/day, divided q12h	10 mg/kg/day, divided q12h	10 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h
		OR				
Chloramphenicol ^g	25 mg/kg/day, q24h	50 mg/kg/day, q12h	25 mg/kg/day, q24h	50 mg/kg/day, q12h	25 mg/kg/day, q24h	50 mg/kg/day, q12h

B. Therapy for severe^a anthrax when meningitis can be ruled out^b

Duration of therapy: For ≥ 2 –3 wk, until clinical criteria for stability are met (see text). Will require prophylaxis to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 6E).

1. A bactericidal antimicrobial**a. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown**

	32–34 wk Gestational Age		34–37 wk Gestational Age		Term Newborn Infant	
	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age
Ciprofloxacin IV	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h
		OR				
Meropenem IV	40 mg/kg/day, divided q8h	60 mg/kg/day, divided q8h	60 mg/kg/day, divided q8h	60 mg/kg/day, divided q8h	60 mg/kg/day, divided q8h	60 mg/kg/day, divided q8h
		OR				
Levofloxacin IV	—	—	—	—	—	—
		OR				
Imipenem ^c IV	40 mg/kg/day, divided q12h	50 mg/kg/day, divided q12h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h
		OR				
Vancomycin IV (dosing based on serum creatinine for infants ≥ 32 wk gestational age). Follow vancomycin serum concentrations to modify dose.		Serum creatinine <0.7 Serum creatinine 0.7–0.9 Serum creatinine 1–1.2 Serum creatinine 1.3–1.6 Serum creatinine >1.6		15 mg/kg/dose 20 mg/kg/dose 15 mg/kg/dose 10 mg/kg/dose 15 mg/kg/dose		q12h q24h q24h q24h q48h
		Begin treatment with a 20-mg/kg loading dose				
		OR				

b. Alternatives for penicillin-susceptible strains

Penicillin G IV	200 000 U/kg/day, divided q12h	300 000 U/kg/day, divided q8h	300 000 U/kg/day, divided q8h	400 000 U/kg/day, divided q6h	300 000 U/kg/day, divided q8h	400 000 U/kg/day, divided q6h
		OR				
Ampicillin IV	100 mg/kg/day, divided q12h	150 mg/kg/day, divided q8h	150 mg/kg/day, divided q8h	200 mg/kg/day, divided q6h	150 mg/kg/day, divided q8h	200 mg/kg/day, divided q6h

PLUS**2. A protein synthesis inhibitor**

Clindamycin IV	10 mg/kg/day, divided q12h	15 mg/kg/day, divided q8h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h
		OR				
Linezolid IV ^e	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h
		OR				
Doxycycline IV (loading dose 4.4 mg/kg) ^{106,107}	—	—	—	—	4.4 mg/kg/day, divided q12h	4.4 mg/kg/day, divided q12h
		OR				
Rifampin IV ^f	10 mg/kg/day, q24h	10 mg/kg/day, q24h	10 mg/kg/day, q24h	10 mg/kg/day, q24h	10 mg/kg/day, q24h	10 mg/kg/day, q24h

C. Oral follow-up combination therapy for severe^a anthrax

Duration of therapy: to complete a treatment course of 10–14 days or greater. May require prophylaxis to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 6E, Postexposure Prophylaxis).

1. A bactericidal antimicrobial**a. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown**

	32–34 wk Gestational Age		34–37 wk Gestational Age		Term Newborn Infant	
	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age
Ciprofloxacin^h PO	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h
		OR				
Levofloxacin PO	—	—	—	—	—	—
		OR				

b. Alternatives for penicillin-susceptible strains

APPENDIX 6 Continued

Amoxicillin PO ^{108–111}	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h
		OR				
Penicillin VK PO	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q6–8h

PLUS

2. A protein synthesis inhibitor

Clindamycinⁱ PO	10 mg/kg/day, divided q12h	15 mg/kg/day, divided q8h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h
		OR				
Doxycycline ^j PO (loading dose 4.4 mg/kg)	—	—	—	—	4.4 mg/kg/day, divided q12h	4.4 mg/kg/day, divided q12h
		OR				
Linezolid PO ^e	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h	30 mg/kg/day, divided q8h

OR

D. Treatment of cutaneous anthrax without systemic involvement

Duration of therapy:

For naturally acquired infection: 7–10 days

For a biological weapon–related event, may require additional prophylaxis for inhaled spores to complete an antimicrobial course of up to 60 days from onset of illness (see Appendix 6E).

1. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown

	32–34 wk Gestational Age		34–37 wk Gestational Age		Term Newborn Infant	
	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age
Ciprofloxacin^h PO	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h
		OR				
Doxycycline ^j PO (Loading dose 4.4 mg/kg)	—	—	—	—	4.4 mg/kg/day, divided q12h	4.4 mg/kg/day, divided q12h
		OR				
Clindamycin ^h PO	10 mg/kg/day, divided q12h	15 mg/kg/day, divided q8h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h
		OR				
Levofloxacin ^h PO	—	—	—	—	—	—

OR

2. Alternatives for penicillin-susceptible strains

Amoxicillin^k PO	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h
		OR				
Penicillin V ^k PO	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q6–8h

E. Postexposure prophylaxis for *Bacillus anthracis*

Duration of therapy: 60 days from exposure

1. For all strains, regardless of penicillin susceptibility or if susceptibility is unknown

	32–34 wk Gestational Age		34–37 wk Gestational Age		Term Newborn Infant	
	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age	0–1 wk of Age	1–4 wk of Age
Ciprofloxacin^h PO	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	20 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h	30 mg/kg/day, divided q12h
		OR				
Clindamycin PO	10 mg/kg/day, divided q12h	15 mg/kg/day, divided q8h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h	15 mg/kg/day, divided q8h	20 mg/kg/day, divided q6h
		OR				
Doxycycline ^j PO (loading dose 4.4 mg/kg)	—	—	—	—	4.4 mg/kg/day, divided q12h	4.4 mg/kg/day, divided q12h
		OR				
Levofloxacin ^h PO	—	—	—	—	—	—

OR

APPENDIX 6 Continued

2. Alternatives for penicillin-susceptible strains

Amoxicillin^k PO	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h
		OR				
Penicillin V ^k PO	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	50 mg/kg/day, divided q12h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q8h	75 mg/kg/day, divided q6–8h

div, XXX; q, every.

Bold font: preferred antimicrobial agent.

Normal font: alternative selections are listed in order of preference for therapy for patients who cannot tolerate first-line therapy, or if first-line therapy is unavailable.

^a Severe anthrax includes anthrax meningitis; inhalation anthrax; or injection, gastrointestinal, or cutaneous anthrax with systemic involvement; extensive edema; or lesions of the head or neck.^b Neonates with irritability, vital sign instability, bulging fontanel, or focal neurologic deficits should be considered to have CNS infection if CSF examination is not possible. Normal CSF may not completely exclude deep brain hemorrhage/abscess.^c Increased risk of seizures associated with imipenem/cilastatin therapy.^d Doripenem is approved in Japan at this dose for the treatment of community-acquired bacterial meningitis in older children.^e Linezolid should be used with caution in newborn infants with thrombocytopenia, as it may exacerbate it. Linezolid use for >14 days may be associated with additional hematopoietic toxicity.^f Rifampin is not a protein synthesis inhibitor; it also may be used in combination therapy based on in vitro synergy.^g Should be used only if other options are not available because of toxicity concerns; obtain chloramphenicol serum concentrations, if possible.^h Safety data are unavailable for fluoroquinolones for duration of therapy >30 days. Tendinopathy and arthralgia have been reported with fluoroquinolone antimicrobial agents in ambulating animals and humans. These problems appear to be much less, if they occur at all, in pediatric patients, especially in newborn infants.^{54,112,113}ⁱ On the basis of in vitro susceptibility data rather than studies of clinical efficacy.^j A single 10- to 14-day course of doxycycline is not routinely associated with tooth staining in older children but may stain developing teeth in neonates.^{40,41,114}^k Be aware of the possibility of emergence of penicillin-resistance during monotherapy with amoxicillin or penicillin.

APPENDIX 7 Diagnostic Assessment and Monitoring for Systemic Anthrax (Based on Recommendations for Adults)

Test	Unique Findings in Systemic Anthrax Infections	
	Initial	Serial Monitoring
Complete blood cell count	Marked hemoconcentration; thrombocytopenia may not be present; white blood cell count frequently normal	Anemia can suddenly develop; thrombocytopenia onset often associated with hemolytic anemia; leukocytosis usually not seen until severe sepsis stage
Electrolytes, blood urea nitrogen, lactate	Decreased sodium; bicarbonate can be normal even with severe sepsis; increased blood urea nitrogen	
Liver panel, serum albumin	Mild transaminitis; hypoalbuminemia related to acute infection	
Prothrombin time (PT), partial thromboplastin time (PTT), D-dimer, Fibrinogen	Normal PT/PTT at admission does not exclude coagulopathy or disseminated intravascular coagulopathy	Low threshold for disseminated intravascular coagulation workup, including haptoglobin, lactate dehydrogenase, fibrin split products. If evidence of hemolytic anemia, assess ADAMTS 13 (von Willebrand factor–cleaving protease).
Erythrocyte sedimentation rate, C-reactive protein	Useful for characterizing inflammatory response	
Gram stain, cultures, serum for toxin assays	Any accessible fluid: blood, sputum, cerebrospinal, urine, wound, gastric ulcers	Cultures usually negative after antimicrobial agents, but toxin may be detectable at multiple time points.
Cardiac enzymes (troponin) +/-B-type natriuretic peptide	Troponin leak as a result of increased cardiac demands from acute infection (especially if atrial fibrillation with rapid ventricular response)	
Electrocardiogram/continuous cardiorespiratory monitoring telemetry	Atrial fibrillation with rapid ventricular response commonly observed.	
Posterior-anterior and lateral chest radiograph	Any abnormality: mediastinal widening may not be seen in inhalation and pleural effusion can be subtle	Daily chest radiographs or other thoracic imaging until pleural effusions are stable or decreasing
Chest CT	Evaluate for severity of pleural effusions, presence of mediastinal widening, and to rule out thromboembolic disease with CT angiography	Repeat if significant clinical status change. Ultrasonography of the chest may be useful for following pleural effusion.
Lumbar puncture	With severe or systemic disease, perform as soon as clinically feasible; meningeal signs are usually not present until late stage, if meningitis is present.	—
Other imaging	As relevant to site of exposure; to evaluate edema, inflammation, and necrosis	—
Echocardiogram	Evaluate for pericardial effusion in addition to myocardial dysfunction.	

APPENDIX 8 Recommendations for Compatibility of Antimicrobial Agents and Breastfeeding

Antimicrobial Agent	US National Library of Medicine LACTMED ^a	Briggs' Pregnancy and Lactation ^b
Amoxicillin	Acceptable to use	Compatible
Ampicillin	Acceptable to use	Compatible
Chloramphenicol	Alternate drug is preferred	Potential toxicity
Ciprofloxacin	Short-term ^c use is acceptable	Limited human data—potential toxicity
Clindamycin	Not a reason to discontinue breastfeeding Alternate drug is preferred	Compatible
Doxycycline	Short-term use is acceptable Avoid prolonged ^d or repeat courses	Compatible
Imipenem	Acceptable to use	Limited human data—probably compatible
Levofloxacin	Short-term ^c use is acceptable	Limited human data—probably compatible
Linezolid	Not a reason to discontinue breastfeeding	No human data—potential toxicity
Meropenem	Not expected to cause adverse effect	No human data—probably compatible
Moxifloxacin	Short-term ^c use is acceptable	No human data—probably compatible
Penicillin	Acceptable to use	Compatible
Rifampin	Not expected to cause adverse effects	Compatible

^a toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT.^b Briggs GG, Freeman RK, Yaffe SJ, eds. *Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk*. 9th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2011.^c 7–14 days.^d More than 14 days.

Pediatric Anthrax Clinical Management: Executive Summary

.....

- *Clinical Report*

CLINICAL REPORT

Pediatric Anthrax Clinical Management: Executive Summary

The use of *Bacillus anthracis* as a biological weapon is considered a potential national security threat by the US government. *B anthracis* has the ability to be used as a biological weapon and to cause anthrax, which can rapidly progress to systemic disease with high mortality in those who are untreated. Therefore, clear plans for managing children after a *B anthracis* bioterror exposure event must be in place before any intentional release of the agent. This document provides a summary of the guidance contained in the clinical report (appendices cited in this executive summary refer to those in the clinical report) for diagnosis and management of anthrax, including antimicrobial treatment and postexposure prophylaxis (PEP), use of antitoxin, and recommendations for use of anthrax vaccine in neonates, infants, children, adolescents, and young adults up to the age of 21 years (referred to as “children”).

Key considerations in a mass *B anthracis* exposure scenario include the following:

1. Public health authorities will determine the presence and extent of a bioterror event. Information of importance to health care providers and the public will be made available as soon as possible by the Centers for Disease Control and Prevention (CDC), including information posted on the CDC Anthrax Web site: www.cdc.gov/anthrax.
2. Within 48 hours of exposure to *B anthracis* spores, public health authorities plan to provide a 10-day course of antimicrobial prophylaxis to the local population, including children likely to have been exposed to spores (Appendix 1). Public health officials will provide information about points of dispensing locations that will distribute antibiotic agents.
3. Within 10 days of exposure, public health authorities plan to further define those who have had a clear and significant exposure and will require an additional 50 days of antimicrobial PEP, as well as beginning the 3-dose anthrax vaccine, anthrax vaccine adsorbed (AVA [BioThrax, Emergent BioSolutions, Rockville, MD]) series for children. Because there are insufficient data for the anthrax vaccine in children, it will be made available under an Investigational New Drug protocol. For children younger than 6 weeks of age (who are not candidates for AVA), antimicrobial prophylaxis should begin immediately, but the vaccine series should be delayed until the child reaches 6 weeks of age.
 - A local adverse event after receiving a previous dose of AVA is not a contraindication to receiving additional doses, although the

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ABBREVIATIONS

AVA—anthrax vaccine adsorbed

CDC—Centers for Disease Control and Prevention

PEP—postexposure prophylaxis

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subsequent dose should be administered at an alternate site and closely monitored.

- Although not strictly contraindicated, AVA should not be coadministered routinely with standard childhood vaccinations during an anthrax event. Immunization of children exposed to aerosolized *B anthracis* spores with AVA is a priority, above routine immunizations. Although data are not available in children regarding the types and frequency of adverse events after immunization, or whether administering AVA as soon as a few days after the receipt of routine immunizations will lead to an increased frequency of adverse events, the benefits of AVA in children exposed to aerosolized *B anthracis* spores are currently believed to outweigh these risks. Routine immunizations should resume 4 weeks after the last AVA dose.
4. Anthrax may occur in different clinical forms, any of which may progress to systemic disease. Treatment will vary by clinical manifestation. The diagnosis of anthrax can be made by physical findings, as described in the clinical report, in conjunction with Gram stain and culture, or by a rapid molecular test for anthrax, currently under development at the CDC. The CDC Web site provides guidance on diagnostic specimens to obtain for the different clinical presentations of anthrax, at www.cdc.gov/anthrax/labs/recommended_specimen.html. Guidance for diagnostic assessment and monitoring with clinical, laboratory and imaging evaluations is also provided in the clinical report (Appendix 7).
 - Cutaneous anthrax without systemic involvement that occurs in the context of an anthrax bioterror event should be treated with a single oral antimicrobial agent (Appendix 2).
 - Inhalation, gastrointestinal, or other systemic disease without meningoencephalitis should be treated with at least 2 intravenous antimicrobial agents: a bactericidal agent and a protein synthesis inhibitor (Appendix 3), with the provision of oral step-down therapy for children whose signs and symptoms of systemic infection have resolved (Appendix 5).
 - Systemic disease with possible or confirmed meningoencephalitis should be treated with 3 intravenous antimicrobial agents with adequate central nervous system penetration, including 2 bactericidal agents and a protein synthesis inhibitor (Appendix 4), for at least 2 weeks, and until all clinical signs and symptoms, supported by laboratory and imaging data, document resolution of inflammation associated with the infection.
 - Antimicrobial agent doses for term and preterm neonates are provided in Appendix 6 for cutaneous and systemic infections as well as for PEP.
 - Anthrax systemic infection is generally not considered contagious, and Standard Precautions should be used for routine patient care. Cutaneous anthrax may be contagious on direct contact of the lesions for the first 24 hours of effective antimicrobial therapy, supporting the use of Contact Precautions during that time.
 5. Either Anthrax Immune Globulin or raxibacumab antitoxin is indicated in patients with anthrax systemic disease, particularly nonmoribund children with severe disease, including those with new onset of organ system failure. Dosing guidelines for children will be available on package labels at the time antitoxin is shipped to the site of the bioterror exposure. Raxibacumab is approved by the US Food and Drug Administration for use in adults and children for the treatment or prevention of anthrax. On the basis of animal studies, pediatric population pharmacokinetic modeling was performed by the manufacturer, and proposed weight-based doses for children are provided on the package label (www.accessdata.fda.gov/drugsatfda_docs/label/2012/125349s000lbl.pdf). Anthrax Immune Globulin is not currently approved by the Food and Drug Administration and will need to be administered under an Investigational New Drug application or Emergency Use Authorization during a mass exposure event.
 6. Corticosteroids should be used in children with more severe systemic disease, particularly those with meningoencephalitis, in doses that are consistent with those currently used for meningitis (dexamethasone, 0.6 mg/kg per day in divided doses every 6 hours for 4 days).
 7. Once therapy has been completed for any form of systemic or cutaneous anthrax infection in children involved in an aerosol *B anthracis* dispersal event, appropriate oral antimicrobial agents as PEP should be provided to complete a full 60 days of therapy.
 8. Unless breastfeeding mothers have untreated cutaneous lesions on their breasts, breastfeeding should continue for infants of mothers who require antimicrobial treatment or prophylaxis or anthrax vaccine (Appendix 8).
 9. To optimally manage children during an anthrax bioterror event, the

ready availability and bidirectional flow of information between public health officials and pediatric health care providers, as well as clear recommendations and consistent messaging to the public from public health officials and

health care providers will be extremely important. Information will be provided on the CDC Web site, www.cdc.gov/anthrax, as well as through the American Academy of Pediatrics. As pediatricians are trusted sources of information,

the medical home can support adherence to prophylactic antimicrobial regimens, decrease panic among parents and caregivers, and possibly save lives in the midst of a public health emergency.

LINKS TO APPENDICES

Pediatric Anthrax Clinical Management Appendices are ordered based on severity of disease to offer easy access in the event of a public health emergency.

Appendix 1. Postexposure Prophylaxis for *B anthracis* (for Children 1 Month of Age and Older)

Appendix 2. Treatment of Cutaneous Anthrax Without Systemic Involvement (for Children 1 Month of Age and Older)

Appendix 3. Combination Therapy for Systemic Anthrax When Meningitis Can Be Ruled Out (for Children 1 Month of Age and Older)

Appendix 4. Triple Therapy for Systemic Anthrax (Anthrax Meningitis or Disseminated Infection and Meningitis Cannot Be Ruled Out) for Children 1 Month of Age and Older

Appendix 5. Oral Follow-up Combination Therapy for Severe Anthrax

(for Children 1 Month of Age and Older)

Appendix 6. Dosing in Preterm and Term Neonates 32 to 44 Weeks' Postmenstrual Age (Gestational Age Plus Chronologic Age)

Appendix 7. Diagnostic Assessment and Monitoring for Systemic Anthrax (Based on Recommendations for Adults)

Appendix 8. Recommendations for Compatibility of Antimicrobial Agents and Breastfeeding

Pediatric Care Recommendations for Freestanding Urgent Care Facilities

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- *Policy Statement*

POLICY STATEMENT

Pediatric Care Recommendations for Freestanding Urgent Care Facilities

abstract

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Treatment of children at freestanding urgent care facilities has become common in pediatric health care. Well-managed freestanding urgent care facilities can improve the health of the children in their communities, integrate into the medical community, and provide a safe, effective adjunct to, but not a replacement for, the medical home or emergency department. Recommendations are provided for optimizing freestanding urgent care facilities' quality, communication, and collaboration in caring for children. *Pediatrics* 2014;133:950–953

INTRODUCTION

Urgent care for children, as a segment of the current health care industry, continues to grow in number of facilities, variety, and scope. The Urgent Care Association of America estimates that there are 4500 urgent care facilities (private communication, Urgent Care Association of America, 2013) at which more than 150 million adult and pediatric visits occur annually in the United States.¹ The descriptors “urgent care” and “urgent care facility (or center)” have been used in a variety of ways, from describing after-hours or sick visits provided in a primary care office or clinic to the provision of hospital-based acute care in a non-emergency department setting. This policy statement addresses acute care provided to sick or injured children in a freestanding setting specifically designated for that purpose and does not address hospital-based urgent care facilities, hospital-based or freestanding emergency departments, or retail-based clinics.²

BACKGROUND

Urgent care typically focuses on providing acute assessment and management of mildly or moderately sick or injured patients, with an emphasis on rapid service and low cost. Freestanding urgent care facilities typically provide unscheduled visits but may also allow patients and families to make an appointment. Business models include individual businesses, franchises, affiliates of a specific health insurer, or subsidiaries of a hospital, among others. Facilities operating as part of a hospital system will probably fall within that larger administrative structure and include shared computerized imaging, laboratory facilities, medical records, and other resources. Most urgent care facilities have at least 1 physician on staff.³ Plain

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KEY WORDS

pediatrics, urgent care, medical home, emergency care, health services

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radiography, suturing of uncomplicated lacerations, splinting of uncomplicated musculoskeletal injuries, and simple laboratory tests are typically offered. Some provide such nonacute services as immunizations and preparticipation sports physical examinations. One of the principal challenges of urgent care is maintaining an appropriate and predetermined scope of practice, because patients with true emergencies may seek care at urgent care facilities; this confusion is probably exacerbated by varying definitions of urgent care. Regulation of freestanding urgent care centers varies greatly between the states, ranging from little oversight to actual prohibition of the use of the term “urgent care” except by emergency centers.⁴ Screening of all patients for emergency medical conditions and other requirements of the Emergency Medical Treatment and Labor Act apply to hospital-owned freestanding urgent care facilities if either the center is licensed as an emergency department, it is advertised as providing care for emergency medical conditions on an urgent basis, or at least one-third of its outpatient visits are for treatment of emergency medical conditions, as judged by the Centers for Medicare and Medicaid Services, on an urgent basis without a previously scheduled appointment.^{5,6}

RECOMMENDATIONS

As the role of freestanding urgent care facilities in pediatric care evolves, it is important that they maintain the highest standards of care. Despite the growth in pediatric urgent care, there is little existing literature beyond professional policy statements and industry white papers on the subject. Research on the nature, scope, quality, and outcomes of pediatric urgent care is scant.^{3,7,8} With these limitations, the

recommendations here represent expert consensus by leaders in pediatric emergency medicine and related fields. Given its growing importance, a better understanding of pediatric urgent care should be an important focus for health service researchers.

Emergency Preparedness

Freestanding urgent care facilities serving children should be capable of providing timely assessment, initial resuscitation, and stabilization and be able to initiate transfer of pediatric patients who need a higher level of care. This includes children with medical, traumatic, and behavioral or mental health emergencies. Staff members at freestanding urgent care facilities should have the training, experience, and skills necessary to initiate pediatric life support during all hours of operation. Simulation or mock codes, with scenarios that are complete from patient presentation to departure, are often an important component of pediatric emergency preparedness. Triage, transfer, and transport agreements should be prearranged with definitive care facilities that are capable of providing the appropriate level of care based on the acuity of illness or injury of the child. Local emergency medical services providers should be familiar with the facility's physical plant and should familiarize urgent care facility staff with their pediatric capabilities. Programs to monitor and improve the quality of care for children with emergencies should be in place. Although written for the primary care provider, the American Academy of Pediatrics policy statement “Preparation for Emergencies in the Offices of Pediatricians and Pediatric Primary Care Providers” offers excellent guidance for preparation, recognition, and response to children needing emergency care in the urgent care facility setting.⁹

Scope of Care

Freestanding urgent care facility operators must give careful thought and planning to the scope of care that they can and should provide to pediatric patients. This includes evidence-based, patient- and family-centered, predetermined approaches to common pediatric complaints, including fever, asthma exacerbations, lacerations, gastrointestinal tract complaints, potential fractures, and other musculoskeletal injuries. Principles guiding the extent of evaluation and management of other complaints should be established. Urgent care facilities should be capable of managing children with special needs. Recognition and management of child abuse or neglect and other aspects of interpersonal violence should be addressed. Guidance regarding conditions that are or are not appropriate to the facility should be readily available to the public, including parents, referring physicians, and other referral sources, such as triage nurse telephone services. This should include guidance on when even a common pediatric complaint is too severe to be appropriate for urgent care, such as injuries or illnesses that may warrant hospitalization, advanced imaging, or invasive procedures. The timing and availability of child-appropriate equipment, on-site and off-site laboratory testing, and imaging must be taken into consideration. Planning should include setting limits on the intensity and scope of care and predetermined systems for handovers of care when those limits are reached or the facility is closing.

Facilities must have predetermined plans for addressing requests for patient care, including those involving children with emergency medical conditions, occurring before or after usual hours of operation, including when staff members are physically

present. Signage and directions to nearby emergency facilities can be especially helpful to those seeking care when no facility staff are present.

The Medical Home

Urgent care facilities should complement and support the medical home model,¹⁰ providing some services not routinely available in the medical home and providing an alternative for acute care should the medical home be unavailable. They should not routinely provide continuity care to children and should avoid appearing as a replacement for the primary care provider. Urgent care facilities should collaborate with primary care providers as referral centers for patients with acute health concerns. Referring providers should provide necessary clinical information to the freestanding urgent care facility and be available to provide consultation and context for their patients' management. Whether a patient is referred or not, appropriate records should be kept. Communication with the medical home should be prompt and seamless. Medical homes must provide easily accessed channels for this communication. Providers who refer children to a freestanding urgent care facility should verify adherence to these recommendations with the facility's leadership and should expect high-quality care for their patients.

Staffing

Freestanding urgent care facilities serving children must be staffed by providers and staff with the training and experience to manage children who are seeking urgent care and to initially assess and manage, resuscitate if needed, and transfer children who are seeking emergency care from the urgent care setting. Educational opportunities directed at clinicians or

administrators providing urgent care for children are needed. Nonphysician providers should have meaningful oversight by appropriate physicians; even when not legally required, collaboration with a qualified physician is desirable. A clinician–manager empowered to address off-hours questions about imaging, laboratory tests, prescriptions, and the like should be designated.

Participation in Systems of Care

Freestanding urgent care facilities provide service that can enhance pediatric care in many communities. Therefore, they should be an integral part of community systems of care. Area health departments, medical societies, and other professional groups should provide appropriate lines of communication and avenues for this participation. Facility-specific disaster preparedness preparations should be in place. In addition, urgent care facilities may be important participants in local and regional disaster plans by providing syndromic surveillance to assist in identification of disasters and epidemics, pediatric primary care services when disaster disrupts the medical home, and countermeasures and patient education in the case of actual or potential outbreaks.

Urgent care facilities should have transfer arrangements with area hospitals capable of providing pediatric or adult emergency care as necessary. Providers should be able to distinguish, ideally via predetermined criteria and in conjunction with families, which patients need emergency ambulance transfers, which need non-emergency ambulance-based transfers, and which may be transferred by other means, such as private vehicle. Planned coordination with local emergency medical services is essential. Appropriate payment should be made to both facilities when a patient is

transferred from a medical home to an urgent care facility or from an urgent care facility to an emergency department or other facility.

Medical professionals providing oversight to freestanding urgent care facilities serving children should regularly review facility adherence to this policy statement. Accreditation by external reviewers of urgent care facilities serving children should include meaningful assessment of quality measures and performance of appropriate pediatric care.

CONCLUSIONS

Well-managed freestanding urgent care facilities can enhance the provision of urgent services to the children of their communities, be integrated into the medical community, and provide a safe, effective adjunct to, but not a replacement for, the medical home. Urgent care facilities serving children should be able to rapidly assess, begin stabilization, and initiate transfer of children with emergencies. Consistent oversight, planning, and quality monitoring and improvement are crucial. The scope of care offered to children should be well defined and well communicated. Providers and staff must have the training and experience to manage children. There remains a great need for research on the role of urgent care in pediatrics. Educational opportunities at the student, resident, fellow, or continuing medical education level involving pediatric urgent care are minimal and should be developed as more and more pediatricians and other health care providers are employed by, provide oversight to, or work collaboratively with urgent care facilities. Accreditation of urgent care facilities serving children should include meaningful assessment of quality measures and performance of appropriate pediatric care.

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The Pediatrician's Role in the Evaluation and Preparation of Pediatric Patients Undergoing Anesthesia

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- *Policy Statement*

POLICY STATEMENT

The Pediatrician's Role in the Evaluation and Preparation of Pediatric Patients Undergoing Anesthesia

abstract

FREE

Pediatricians play a key role in helping prepare patients and families for anesthesia and surgery. The questions to be answered by the pediatrician fall into 2 categories. The first involves preparation: is the patient in optimal medical condition for surgery, and are the patient and family emotionally and cognitively ready for surgery? The second category concerns logistics: what communication and organizational needs are necessary to enable safe passage through the perioperative process? This revised statement updates the recommendations for the pediatrician's role in the preoperative preparation of patients. *Pediatrics* 2014;134:634–641

INTRODUCTION

Primary care providers, including pediatricians, are frequently called on to evaluate and psychologically prepare patients and families before a child undergoes a procedure requiring anesthesia or sedation. This policy statement identifies that primary care provider's preoperative goals of care are as follows: to clearly define the child's medical issue; to delineate the physiologic effects and limitations imposed by each condition; and to optimize the management of any comorbid conditions. Furthermore, the policy recommends that pediatricians facilitate essential communication about the historical, physical, and laboratory findings in children with unusual or complex medical histories with the anesthesiologist and/or surgeon to ensure safe perioperative care.

The objectives of the present statement were twofold:

1. to describe to pediatricians the issues of concern to anesthesiologists and surgeons to improve the effectiveness of medical consultations in preparing pediatric patients and families for the perioperative period; and
2. to present information that will encourage and facilitate communication among surgeons, anesthesiologists, medical subspecialists, pediatricians, and other primary care providers.

ROLE OF THE PEDIATRICIAN IN THE PREOPERATIVE PREPARATION

General Approach

The primary steps in preoperative preparation are to determine whether the child is in the best possible state of health, given the child's underlying

SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE

KEY WORDS

anesthesia, pediatric anesthesia, pediatric surgery, perioperative, preoperative

ABBREVIATIONS

DNR—do not resuscitate

MH—malignant hyperthermia

NPO—nil per os

OR—operating room

PONV—postoperative nausea and vomiting

PPIA—parental presence during induction of anesthesia

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medical condition, and to manage any concurrent acute interceding illness. The key concept is that the patient's medical condition should be "optimized" when he or she presents to the operating room (OR). The American Society of Anesthesiologists has an established risk-stratification system (Table 1).¹ Class 1 and class 2 are considered low risk. The goal of preoperative preparation is to bring patients from a higher risk stratum to a lower one when possible or, at least, to ensure that the patient is in the best condition within his or her physical status category.

The second step in preparing patients is to educate the family about the process of going to the OR and to help them advocate for a process that works best for them and their child. Preparation for surgery has many facets.² There is no "standard" procedure for preparing children for surgery, and available resources vary greatly from one institution to another. Options for family and child preparation may include Internet-based information, tours of the perioperative environment, coping/relaxation instruction, and interventions by child life specialists.³ General information can be found in video or book format, although content and accuracy vary.⁴ Some hospitals allow parental presence during induction of anesthesia (PPIA). However, PPIA is

not a universal practice and is always at the discretion of the anesthesiologist involved in a particular case. Although beneficial to some families and practiced in a number of centers, PPIA is not effective in relieving anxiety in the children, especially if the parent(s) is anxious.^{5–7} PPIA can be stressful to parents, and the pediatrician should thus make sure families know that PPIA may be an option but is never mandatory.

In many cases, children and their families benefit from preoperative sedation. Younger children (2–5 years of age) and patients who have been to the OR before are at higher risk of being stressed and uncooperative during the induction of anesthesia.⁸ In addition, some patients will suffer from postoperative behavioral changes, including sleep difficulties, which may present to the pediatrician in the weeks after surgery. Recent studies have concluded that the likelihood of these maladaptive behaviors is higher if the child is anxious preoperatively.⁹ Pediatricians need to be aware of the policies surrounding PPIA and preoperative sedation at the operative facilities to which they refer their patients. Parents should be encouraged to ask the anesthesia team about available options for preinduction sedation and PPIA. This information can empower them to better advocate for their child.

Most anesthesia departments will obtain informed consent for the anesthesia, separate from that for the procedure. For most minors, the parents will give informed consent (technically, informed permission). Adolescents can participate, to varying extents, in the process by giving assent to care. Pediatricians should encourage adolescent patients to ask questions to make sure they understand what is planned. In cases in which the patient can make no meaningful objection (emergency or other nonelective procedure), then the option to assent or decline care should not be presented.¹⁰

Currently, there is concern about the potential negative effects of general anesthesia in neurologic development, especially in children aged <2 years who undergo multiple procedures.^{11–13} Pediatricians need to stay informed of this evolving area of inquiry. Although no firm guidelines exist, some experts have proposed delaying purely elective procedures as long as possible.¹⁴ The long-term effects of anesthesia on the developing human brain are still unknown, but there is broad agreement that limiting exposure to general anesthesia in infants is a wise policy.

The Preanesthesia Consultation

Patients with complex medical and surgical conditions can benefit from a thorough preoperative assessment by an anesthesia care provider. Ideally, these preoperative evaluations take place in advance of the day of surgery, to avoid last-minute cancellations that occur because of missing data critical to optimizing the patient's condition for surgery. Many anesthesia departments have consultation clinics to provide a common touch point for the pediatrician, anesthesiologist, surgeon, consultants, and family. If no such clinic is available, then the pediatrician and family should pose their questions about the perioperative preparation of the child directly to an anesthesiologist in the department (or group) that will be caring for the patient. Because the specific anesthesiologist assigned to the case may not be known more than a day ahead of the surgery, contact with an anesthesia provider will often be made through the anesthesiology department. Examples of criteria for preoperative anesthesia consultation are shown in Table 2.^{15,16}

Information of Importance to the Anesthesiologist and Surgeon

History of the Present Illness

This part of the history is usually clear, but medical factors leading to the need

TABLE 1 ASA Physical Status Classification System

ASA physical status 1: A normal healthy patient
ASA physical status 2: A patient with mild systemic disease
ASA physical status 3: A patient with severe systemic disease
ASA physical status 4: A patient with severe systemic disease that is a constant threat to life
ASA physical status 5: A moribund patient who is not expected to survive without the operation
ASA physical status 6: A declared brain-dead patient whose organs are being removed for donor purposes

ASA, American Society of Anesthesiologists.
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TABLE 2 Examples of Patients Who Should Be Seen for a Preanesthesia Consultation^{15,16}

Children who are having the following operations:

- Complex spine surgeries
- Airway reconstruction
- Major chest surgery (include cardiac)
- Major abdominal surgery
- Major neurosurgery

Children with the following medical conditions:

- Complex heart disease, history of heart failure, or pacemaker dependence
- Serious respiratory disease, such as severe asthma and cystic fibrosis and patients requiring ventilator support or oxygen therapy
- Complex airway patients, including those with craniofacial syndromes and those with a history of being difficult to intubate
- Patients with severe obstructive sleep apnea
- Muscular dystrophy, mucopolysaccharidoses, or any progressive neuromuscular disorders
- Cervical spine instability and patients in a neck brace
- Hunter syndrome and Hurler syndrome
- Morbid obesity
- Living related organ donors
- Transplant recipients
- Patients presenting with complex ethical issues; for example, religious objections to blood transfusion or end-of-life decisions (eg, DNR orders)
- Complex pain or psychosocial issues that affect perioperative care

for surgery are important, including the intended effect of the operation on health and future care.

Medical History

The details of the patient's medical history are not always apparent to the perioperative care team; therefore, the pediatrician's detailed knowledge of the patient's medical history is an especially important area in which he or she can improve overall care for a patient. For example, pediatrician input has been shown to frequently modify the perioperative plan in children undergoing dental procedures.¹⁷ Planning for anesthesia benefits from communication about neurologic development and function, airway anomalies (eg, difficult intubations, history of airway surgery), cardiac and pulmonary function (including sleep apnea as well as

lung disease), coagulation history, endocrine and renal diseases, and history of exposure to chronic opioids, anesthetics, and sedatives. Motion sickness is a risk factor in adults for postoperative nausea and vomiting (PONV) and is very likely a predictor in children as well. This history should be noted, as should a history of PONV with previous surgeries.¹⁸ General psychosocial history can guide perioperative management. Conditions such as severe anxiety or posttraumatic stress disorder or conditions that impair the child's ability to process information (eg, attention-deficit disorder) or interact with strangers under stressful conditions (eg, oppositional defiant disorder, autism spectrum disorders) should be conveyed to the anesthesia care team. Before elective procedures, consultation with a psychologist to aid in preparing the family and child with these severe cognitive and emotional disorders may be helpful as well.

Medications

The most common problem regarding perioperative medication administration is the misunderstanding that nil per os (NPO, or withholding oral foods/fluids) intervals do not necessarily include medications. Most regularly prescribed medications can be taken with a sip of water on the day of surgery and not violate NPO standards. Conversely, many nonprescription medications and herbal supplements may pose potential risk of bleeding or drug interaction.^{19,20} Over-the-counter medications and supplements should be stopped before surgery, unless there is specific reason to continue them (eg, aspirin in certain patients with cardiac conditions). The exact timing will depend on the medication or supplement involved.

Family History

Four items of family history are particularly important: malignant hyperthermia (MH), prolonged paralysis after

receiving succinylcholine (pseudocholinesterase deficiency), bleeding diathesis, and PONV. In the cases of MH and pseudocholinesterase deficiency, appreciation of either of these entities will dictate the avoidance of specific anesthetic agents, the use of which can result in potentially catastrophic effects in predisposed patients. A family history of spontaneous or postsurgical bleeding may indicate the need for hematologic investigation before certain procedures. As mentioned previously, a family history of PONV is less specific than a history of MH, because influences are multifactorial, but this information may help the anesthesiologist address the family's questions regarding anesthetic technique and prophylactic medications.

Physical Examination

The pediatrician's examination sets a baseline against which the perioperative physical status can be compared. Highlighting neurologic findings, cardiac murmurs, rashes, wheezing, congenital anomalies, and vital signs is helpful to perioperative care providers.

Pertinent Laboratory Evaluation

There is no role for routine laboratory testing of healthy children undergoing procedure with minimal risk of blood loss or for neurologic, cardiac, or pulmonary compromise. Some centers require hemoglobin testing for infants and for patients having surgery in which blood loss is expected. In healthy children, laboratory and radiologic testing should be limited to situations in which the history or physical examination raises a specific possibility of risk. For patients with specific illnesses, testing serves the purpose of establishing a baseline and determination if the patient's underlying condition is appropriately controlled before inducing the perturbations of anesthesia and surgery.

Many institutions have policies that require preoperative pregnancy testing

for all postmenarcheal females on the morning of surgery. It is helpful to warn patients and families that this testing may take place and is not a personal judgment but rather a matter of routine.

SPECIAL ISSUES FOR PRIMARY HEALTH CARE PROVIDERS: ANESTHESIA AND COEXISTING HEALTH PROBLEMS

Cardiac Disease

A child with a new murmur that does not have the characteristics of an “innocent murmur” should be evaluated by a cardiologist to determine the presence of an intracardiac shunt and/or obstruction to flow.

Children with known congenital heart disease, such as a history of “repaired” tetralogy of Fallot or pulmonary hypertension, should be evaluated by a cardiologist before anesthesia; the time interval necessary depends on the severity of the child’s disease and/or the need for possible cardiac intervention before anesthesia to optimize the child’s physiologic condition. The management of anticoagulation for patients with prosthetic valves requires coordination with a cardiologist (and often a hematologist) well in advance of surgery. Note should be made of pacemakers (and any perioperative adjustments may be made by a cardiologist), pulmonary hypertension (degree and duration), and any unusual electrocardiographic findings (eg, prolonged QTc interval).^{21,22} Patients with any of these issues should have been evaluated by a pediatric cardiologist before anesthesia and surgery to ensure optimal condition and management during the perioperative period.

Airway Anomalies

Few things are more dangerous than difficulty in maintaining a patent airway or being unable to intubate a patient. Therefore, it is imperative that the pediatrician inform the anesthesia team

of all patients with airway disorders. “Red flag” conditions include: previous difficulties with intubation or mask ventilation, Pierre Robin syndrome, Treacher Collins syndrome, Goldenhar syndrome, Down syndrome, Klippel-Feil syndrome, mucopolysaccharidoses, previous airway or cervical spine surgery, prolonged neonatal intubation, and stridor at rest.

Respiratory Disease

Asthma, cystic fibrosis, and other chronic lower respiratory disease all merit mention in the preoperative evaluation. The following are important to the anesthesiologist: use of steroids in the recent past, a history of chest or airway surgery, a history of bronchopulmonary dysplasia, upper airway malformation, and history of sleep apnea. In an otherwise healthy child, the presence of an acute upper respiratory tract infection without systemic or lower respiratory tract symptoms is not usually grounds for cancellation of surgery. Conversely, upper respiratory tract infections that are accompanied by fever, wheezing, or productive cough are likely to lead to cancellation of elective procedures.^{23,24} Patients scheduled for nonemergent procedures who are recovering from respiratory illness in the previous 2 weeks are taken on a case-by-case basis; detailed information provided by the pediatrician concerning the chest and upper airway examination can be very helpful in determining the timing of surgery.

Central Nervous System

Patients with seizure disorders should take their anticonvulsants as scheduled. Notation of the type of seizure, medications, and a brief description of a typical seizure may aid perioperative care providers in recognizing a seizure and speed treatment. Any patient with a baseline neurologic deficit should have that deficit described so that changes could be recognized in the perioperative

period. Increased intracranial pressure (of any extent) has particular implications for perioperative care and should be noted in the history. For children at risk for cervical spine instability (eg, Down syndrome,²⁵ mucopolysaccharidoses,²⁶ severe Ehlers-Danlos syndrome), results of cervical spine radiographs or history of symptomatic instability should be clearly identified for the surgeon and anesthesiologist. Radiographic screening does not predict risk of cervical instability²⁷ in Down syndrome. Thus, all these patients are treated with caution, and parents can be assured that their child will have cervical spine precautions regardless of radiograph results.

Hematologic Disorders

Histories of patients with hemoglobinopathies, such as sickle cell disease, should include medications, any previous serious complications (eg, acute chest syndrome, splenic crisis, aplastic crisis, cholecystitis), and opioid treatment. For children with hemophilia, von Willebrand disease and other factor deficiencies and platelet disorders, a history of complications and treatment algorithms are critical. A plan for perioperative management should be coordinated with the child’s hematologist and clearly delineated. For children with factor V Leiden deficiency or other genetic thrombophilias that increase the risk of deep vein thrombosis, the history should include any thromboembolic events and medications used for treatment. Central nervous system thromboembolic events should be carefully described, along with any residual neurologic deficits. Laboratory studies and preoperative preparations should be tailored to each disorder.

The Former Preterm Infant

When compared with infants born at term, former preterm infants (born at <37 weeks’ gestation) are estimated to be at higher risk of postoperative

apnea and bradycardia after general anesthesia until a postconceptual age of approximately 60 weeks.²⁸ Parents of former preterm infants should be counseled to expect an overnight stay after surgery (pediatricians should check the policy of their local facilities because the exact postconceptual age requiring overnight observation varies slightly from one institution to another). Physical signs in children with sequelae of preterm birth (eg, bronchopulmonary dysplasia, neurologic deficits) should be noted to establish a baseline for comparison and to aid intraoperative planning.

Muscular Diseases

Muscular dystrophies merit special attention because their multisystem effects have profound implications for anesthesia.²⁹ Special approaches to anesthesia, such as the avoidance of exposure to inhaled agents, are often necessary. Young children with hypotonia who do not carry a formal diagnosis should be identified so appropriate precautions can be taken. In many of these cases, mitochondrial inborn errors of metabolism are being considered in the differential diagnosis. In these cases, anesthetic approach and fluid management are different from that for muscular dystrophy; therefore, any relevant data indicating a specific metabolic deficiency are helpful.

Hypertension

Although mild to moderate hypertension does not seem to negatively affect outcome in the perioperative period, 2 issues need to be attended to preoperatively: (1) secondary causes of hypertension need to be identified and corrected before surgical intervention when possible; and (2) antihypertensive medications should be continued through the time of surgery. The exceptions to this rule are the angiotensin-converting enzyme inhibitors, which are generally held

on the day of the procedure.³⁰ The decision to administer these medications should be made with input from the anesthesiologist.

Diabetes Mellitus

For patients with diabetes mellitus, the key perioperative issue is: "how well controlled is the diabetes mellitus?" A patient with poorly controlled diabetes mellitus may need to have elective procedures postponed until blood sugar concentration is controlled.³¹ It is critical to coordinate care with the patient's endocrinologist and anesthesiologist to ensure optimal insulin management during the NPO interval before surgery. Families should be told to expect to arrive especially early on the day of surgery, to allow monitoring of glucose, to adjust insulin administration, and to begin administration of dextrose-containing intravenous fluids.

Morbid Obesity

Morbidly obese patients have potential issues with positioning, airway maintenance, placement of intravenous catheters, and comorbidities, such as obstructive sleep apnea and diabetes mellitus, which raise the risk profile of these patients.³² Baseline height, weight, and BMI should be recorded. If a history of significant sleep disturbance is elicited, consideration should be given to obtaining a sleep study to quantify the degree of obstructive sleep apnea. In general, patients who are morbidly obese would benefit from a consultation with an anesthesiologist and can be counseled that they may have a peripheral intravenous catheter placed before induction of anesthesia.

Patients With Transplanted Organs

Posttransplant patients have invariably undergone many procedures, and this history may result in extreme anxiety surrounding medical interventions. They require special attention to their stress

levels (and possible sedation) preoperatively. Immunomodulatory medications should be continued through the perioperative period, and coordination with the transplant team regarding medication management is helpful.

Inborn Errors of Metabolism

Patients with metabolic disease pose 3 general issues for optimal perioperative management. The first is the effect of the preoperative fast, which may have to be modified (or supplemented with an intravenous glucose infusion). The second issue pertains to the downstream effects of the particular disease, such as seizures, airway involvement, or developmental delay. Finally, the potential adverse effects of intravenous fluids, glucose, and certain medications must be considered. It is helpful for the pediatrician to facilitate early contact between the family, metabolic specialist, and anesthesiologist for careful preoperative planning involving all of these potential problem areas.

Renal Insufficiency/Failure

Three major classes of problems are important perioperatively in patients with renal impairment: electrolyte imbalances, fluid status, and associated medical conditions. Potassium concentrations need to be closely monitored. Hyperkalemia should be noted, and if the potassium concentration is significantly elevated from baseline, it should be treated preoperatively. A history of recent weight gain may signal fluid retention and should be relayed to the anesthesia team. Decreases in exercise tolerance can signal cardiac dysfunction. Underlying causes of renal dysfunction (eg, lupus, metabolic or toxic causes) should be noted for anesthesia providers.

Oncologic Diseases

There are 2 important considerations for patients who have or have had

oncologic diseases. First, patients with a mediastinal mass (most often with a new lymphoma diagnosis) are at risk for lethal airway or great vessel compression on induction of anesthesia.³³ Important signs include the inability to lie supine, dyspnea on exertion, plethora of head and neck, and biphasic stridor. Second, treatments for oncologic diseases can have profound effects on the overall perioperative management. Exposure to chemotherapies, such as bleomycin or doxorubicin, can result in long-term effects, such as pulmonary fibrosis and cardiomyopathy.^{34,35} Radiation treatments can cause fibrosis in multiple tissues, which can result in limited mouth opening and neck movement and can worsen pulmonary fibrosis.³⁶ Hematologic and metabolic perturbations are common during oncologic therapy and should be carefully monitored before surgery. Data regarding any of these factors are important to include with the preoperative evaluation.

Developmental Delay/Autism

The perioperative environment can be confusing and scary for any child, perhaps more so for those with cognitive delays. In addition, evaluation of postoperative pain can be difficult, and parents should be questioned about specific pain behaviors in their child. Difficulties in sensory processing and the social interaction often make the perioperative period difficult for children with autism spectrum disorders. Education of the family and child on the process of anesthesia and surgery is generally helpful. Parents should be queried for advice on how a particular child can be best approached by the

perioperative care team.³⁷ Information on “triggers” for aggressive behavior or comfort items should be communicated in a preoperative note.

Do-Not-Resuscitate Orders for Patients in the OR

The American Academy of Pediatrics, the American Society of Anesthesiologists, and the American College of Surgeons have statements on issues related to do-not-resuscitate (DNR) status during operative interventions.^{38,39} DNR orders will be reviewed with patients and families in light of the expected effects of surgery (eg, blood loss) and anesthesia (eg, intubation, cardiac effects of certain drugs). The family and surgical and anesthesia teams will decide on the best option for managing DNR status, which may include modification, suspension, or continuation for the perioperative period.⁴⁰ Patients need to know that such a discussion will occur before entering the OR.

Religious Considerations

For procedures such as spinal fusions or cranial vault reconstructions, blood transfusions are common. Jehovah's Witness families should meet with the anesthesiologist to review the options for handling hematologic issues. The legal and ethical issues are complex.⁴¹ In the event of life-threatening blood loss, many states allow blood transfusion in minors. The family and anesthesia team should discuss the implications of the law in the state in which surgery will be performed. The family can be reassured that all possible measures to avoid transfusion will be taken. Other religious practice

considerations include requirements for wearing specific clothing, charms, or covering the head. Removal of these items may or may not be required for anesthesia or surgery, and the pediatrician should counsel the family to discuss options with the anesthesia team.

CONCLUSIONS

Pediatricians are in a unique position to help prepare children and their families for surgery and help the perioperative team optimize care. Communication about conditions related to increased risk in the OR and aiding the family to advocate for their child in a stressful situation are valuable contributions to the preoperative preparation of the pediatric patient.

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Physician Health and Wellness

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- *Clinical Report*

CLINICAL REPORT

Physician Health and Wellness

abstract

FREE

Physician health and wellness is a critical issue gaining national attention because of the high prevalence of physician burnout. Pediatricians and pediatric trainees experience burnout at levels equivalent to other medical specialties, highlighting a need for more effective efforts to promote health and well-being in the pediatric community. This report will provide an overview of physician burnout, an update on work in the field of preventive physician health and wellness, and a discussion of emerging initiatives that have potential to promote health at all levels of pediatric training.

Pediatricians are uniquely positioned to lead this movement nationally, in part because of the emphasis placed on wellness in the Pediatric Milestone Project, a joint collaboration between the Accreditation Council for Graduate Medical Education and the American Board of Pediatrics. Updated core competencies calling for a balanced approach to health, including focus on nutrition, exercise, mindfulness, and effective stress management, signal a paradigm shift and send the message that it is time for pediatricians to cultivate a culture of wellness better aligned with their responsibilities as role models and congruent with advances in pediatric training.

Rather than reviewing programs in place to address substance abuse and other serious conditions in distressed physicians, this article focuses on forward progress in the field, with an emphasis on the need for prevention and anticipation of predictable stressors related to burnout in medical training and practice. Examples of positive progress and several programs designed to promote physician health and wellness are reviewed. Areas where more research is needed are highlighted. *Pediatrics* 2014;134:830–835

INTRODUCTION

Physician health and wellness is an issue garnering national interest because of the high prevalence of burnout in medical practitioners and trainees. Burnout takes a steep toll on physicians and has negative effects on patients and health care systems.¹ Research advances detailing the detrimental effects of chronic stress, including impaired immune function, inflammation, elevation of cardiovascular risk factors, and depression,^{2–9} are directly relevant to pediatric practitioners and create a need for organized efforts to address physician health and well-being in the pediatric community. The purpose of this report is to provide an update on the issue of physician health and wellness with regard to how they relate to pediatricians. Rather than reviewing programs already in place to address substance abuse and other serious conditions in distressed

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KEY WORDS

burnout, physician health and wellness, stress, lifestyle change, mindfulness

ABBREVIATIONS

AAP—American Academy of Pediatrics

ACGME—Accreditation Council for Graduate Medical Education

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physicians, this report focuses on forward progress in the field, with an emphasis on the need for prevention and anticipation of predictable stressors related to burnout in medical training and practice. Although specific recommendations are beyond the parameters of this report, examples of positive progress and national programs to promote physician health and wellness will be reviewed.

BURNOUT: THE ANTITHESIS OF WELLNESS

Physician burnout is commonly assessed using the Maslach Burnout Inventory, which uses 3 general scales to measure characteristics of burnout. These include emotional exhaustion, depersonalization, and sense of personal accomplishment.^{10,11} Burnout is higher in physicians than in the general population and peaks during training¹² as well as mid-career.¹³

Prevalence of burnout in pediatrics mirrors rates in other medical specialties (30%–50%),^{14,15} with higher rates documented in specialties such as hematology-oncology, neonatal and intensive care, and pediatric surgery.^{16–19} In a periodic survey of American Academy of Pediatrics (AAP) members ($n = 1616$; response, 63%), 22% of surveyed physicians agreed they were currently experiencing burnout, and 45% agreed they had experienced burnout in the past.²⁰ Burnout has also been documented in pediatric trainees. A longitudinal prospective study of pediatric residents at Stanford University Lucille Packard Children's Hospital showed a significant increase in all burnout characteristics (emotional exhaustion, depersonalization, and sense of personal accomplishment) by February of their internship year, reaching prevalences of 24% to 46% (depending on burnout criteria used). High burnout rates persisted throughout residency training.²¹ Multiple studies have documented high levels of burnout in medical and premedical students.^{22–25}

Drivers of physician burnout are multifactorial and have been widely reported in the literature, and include an expectation of unrealistic endurance, time pressure, excessive work hours, threat of malpractice suits, difficult patients, coping with death, unprocessed grief, sleep deprivation, and unsupportive work environments. Professional demands coupled with personal stressors, such as financial worries, limited free time, isolation, uncertainty, a culture of silence, and a lack of effective stress management skills, further compound burnout risk.²⁶ Even reduction in resident duty hours, instituted by the Accreditation Council for Graduate Medical Education (ACGME) in 2003 in the United States, has had the unintended consequence of increased attending physician workload and decreased teaching time while increasing burnout and job dissatisfaction.²⁷

Ironically, many of the character traits valued in pediatricians, such as compassion, altruism, and perfectionism, also predispose to burnout when clinicians are pushed to mental or physical extremes. Although the warning signs and symptoms may be subtle, burnout is often accompanied by anxiety or depression. Suicidal ideation and, tragically, completed suicide are not uncommon. It is a sobering fact that an estimated 300 to 400 physicians in the United States commit suicide annually. Women physicians are at highest risk, with an estimated relative risk ratio of 2.7 for suicide in relation to the general female population,^{28–30} cause for heightened awareness in pediatrics, a field in which women now make up the majority of trainees.³¹

STIGMA AND SANCTIONS

Recognition of burnout in one's colleagues or in oneself raises challenging questions, especially in light of the relative lack of available resources and the lingering stigma of disciplinary sanctions. In fact, it was only after a 1973 "landmark" policy paper in the *Journal of the*

*American Medical Association*³² linking addictive behavior and other mental health issues in physicians with the term "sick" rather than "disciplinary problems" that The Federation for State Physician Health Programs was developed. The *Journal of the American Medical Association* article offered a rare public glimpse into the closed medical community and acted as a powerful catalyst for change. By 1980, 51 of the 54 medical societies of all states and jurisdictions had authorized or implemented impaired physician programs, mandated to identify, treat, and rehabilitate physicians struggling with burnout-related drug and alcohol addiction.³³ Although these programs have benefitted many physicians, a culture of stoicism still permeates the practice of medicine, slowing progress in the push for a more open dialogue about physician health and wellness.

REDUCING BURNOUT: A SHIFT TO PREVENTION

Recognized steps to reduce physician burnout include: providing physicians and trainees a greater sense of control, absence of role conflict, a sense of fair treatment, positive social support, appropriate financial, institutional, and social rewards, and proper alignment between the values of an individual and his or her workplace.¹⁰

The need for systems-based, rather than individual efforts, to reduce burnout is reflected in 2 important initiatives. The first is the 2009 Joint Commission guidelines mandate that medical staff "...implement a process to identify and manage matters of individual health for licensed independent practitioners which is separate from actions taken for disciplinary purposes."³⁴ The second, specific to the field of pediatrics, is the Pediatric Milestone Project, a major collaborative effort between the ACGME and the American Board of Pediatrics tasked with updating core competencies

in pediatric training. Language in the newly developed Personal and Professional Development competencies speaks directly to cultivation of skills that address burnout prevention and finally shift the perspective toward preventive wellness. For example, the Personal and Professional Development competency identifies a need for regular physical activity, healthy nutrition, and supportive social connections as well as development of skills in stress management, self-awareness, and the ability to engage in help-seeking behaviors to maintain health and well-being. Cultivation of empathy, humanism, and compassion are identified in the new Professionalism competency.^{35,36}

The challenge will be in implementation and measurement of these new competencies, which will require the full engagement of pediatric mentors who place a high value on physician well-being and recognize the importance of preventing burnout at all stages of pediatric training and practice.

PHYSICIAN HEALTH AND WELLNESS IN THE AAP

The mission of the Special Interest Group on Physician Health and Wellness is to raise awareness throughout every level of the AAP and to develop educational programming and resources on physician health and wellness that are accessible to all members. Stewardship of the Special Interest Group transitioned to the Section on Integrative Medicine in 2011. In part, this occurred because a primary educational focus of the Section on Integrative Medicine is preventive health, including core topics such as nutrition, physical activity, healthy sleep, stress management, and self-regulation skills, which provide a useful blueprint for preventive physician health.

THE COMPONENTS OF WELLNESS

Hundreds of studies have confirmed the high prevalence of burnout, yet relatively

few have examined or quantified the characteristics of physician wellness. Some studies have demonstrated that issues such as work-life balance, social and family support, adequate rest, and regular physical activity correlate with career satisfaction, improved sense of well-being, increased empathy, and decreased burnout.^{37,38} As opposed to physicians who neglect their health,³⁹ physicians with healthy lifestyle habits have been perceived as more credible and motivating to their patients and the residents under their supervision.^{40–42} It has been shown that wellness behaviors in physicians are additive; therefore, individuals should be encouraged to adopt a variety of approaches to best suit their individual needs.⁴³

Comparison of 2 AAP periodic surveys (Periodic Survey No. 54 in 2003 and Survey No. 81 in 2012) examined work hours, presence of minor children at home, perceived stress of balancing work/home responsibilities, and satisfaction with amount of time available to spend in several personal activities. In 2012 pediatricians reported less stress balancing home and work than in 2003. This reduction in perceived stress was correlated with reduced work hours and not having minor children at home. In 2012, pediatricians reported higher satisfaction with time to spend with spouse/partner, friends, hobbies, community activities, and spiritual needs.^{44,45}

EXAMPLES OF PROGRESS: CREATING A NATIONAL CULTURE OF PHYSICIAN WELLNESS

Although some programs have been established after tragic losses of colleagues, such as the comprehensive Suicide Prevention and Depression Awareness Program at the University of California, San Diego School of Medicine,²⁸ other residency programs and medical schools in the United States have taken the opportunity to proactively institute comprehensive wellness

programs. Support from administrative faculty leaders has been identified as integral to most of these programs. Some characteristics of these programs include creation of a wellness mission statement for the organization; identification of key components for developing and maintaining wellness; measuring and tracking burnout in residents and faculty; creation of a lecture series on wellness topics; resident support groups early education about stress management; cultivation of resilience; development of a confidential fast-track referral source for mental health services; annual resident retreats focused on health and wellness; raising awareness of the correlation between resident wellness and faculty wellness; online curriculum on self-care and wellness; and selection of primary care physicians unrelated to the training program available to residents for ongoing health care. Example programs include:

- Learner Advocacy and Wellness at the University of Alberta, Edmonton, Canada⁴⁶
- Physician Well-Being Program, William Beaumont Hospitals, Troy Family Medicine Residency Program, Detroit, Michigan¹⁴
- Vanderbilt Wellness Program, Vanderbilt School of Medicine, Nashville, Tennessee⁴⁷
- Resiliency and Wellness Education Program, University of California, San Diego Department of Emergency Medicine⁴⁸
- Integrative Medicine in Residency Program, University of Arizona⁴⁹ and the Pediatric Integrative Medicine in Residency Program, University of Arizona

Collectively, these programs demonstrate the power of developing an organized plan to promote wellness in their physician communities and highlight the importance of institutional efforts to alter the status quo.

NEW FRONTIERS OF WELLNESS: MINDFULNESS IN MEDICINE

Recognition of the detrimental health effects of chronic stress has catalyzed the search for better approaches to stress reduction in physicians. Although numerous lifestyle approaches are under consideration, research on the use of mindfulness in the medical setting currently has substantial supporting evidence. This can be traced back to the early work of Jon Kabat-Zinn, PhD, who has described mindfulness as “conscious, moment-to-moment awareness, cultivated by systematically paying attention on purpose in a particular way.”⁵⁰

Mindfulness as a self-regulation tool aligns with the new ACGME core competencies and has been used by physicians in various formats. Some examples include mindful communication programs that involve meditation, self-awareness exercises, processing of clinical experiences, and appreciative interviews. Reduction in burnout measures, such as depersonalization and emotional exhaustion, and improvements in mindfulness, empathy, and feeling of personal accomplishment were observed.^{51–53} Use of mindfulness has also resulted in significant improvement in burnout scores and mental well-being when offered on a recurring basis as a continuing medical education course,⁵⁴ or as online modules for residents and faculty.^{55,56}

The effect of education in mindful communication has been examined in physicians in a structured training program, which produced 4 main themes of feedback from participants: (1) participants felt a decrease in sense of personal isolation; (2) mindfulness training helped physicians listen more deeply and attend to the patient's concerns more effectively; (3) adaptive reserve was increased; and (4) participants experienced a feeling of greater self-awareness that proved, in many cases,

to be transformative.^{57,58} Mindfulness may also support more thoughtful decision-making and can enhance empathic communication. Precedent in the use of mindfulness exists in law and business, where it is used to reduce reactivity in stressful situations. The use of mindfulness and guided imagery is also gaining acceptance in the military to reduce stress and enhance performance.^{59,60}

One of the few available randomized controlled clinical trials in physician burnout intervention demonstrated substantial decrease of rates of depersonalization, emotional exhaustion, and overall burnout in the treatment group and resulted in improved sense of meaning and engagement in work in 74 practicing internal medicine physicians who attended 9 months of biweekly facilitated discussion groups that incorporated elements of mindfulness, reflection, shared experience, and small group learning.¹⁵ More research is needed to identify programs that will best serve the needs of pediatricians at various stages of training and practice.

CONCLUSIONS

Physician health and wellness is a complex topic, relevant to pediatricians at all stages of training. Advances in our understanding of the harmful effects of chronic stress and consequent shifts in ACGME core competencies prioritizing pediatric resident wellness create a need for programs that will help practicing pediatricians not only keep pace but also become leaders and role models in shaping a healthier culture of pediatric practice.

A primary purpose of this clinical report is to shift the focus from burnout treatment to preventive physician health and wellness and identify factors that will increase career satisfaction and longevity, including promotion of a balanced lifestyle that includes physical

activity, healthy nutrition, restorative sleep, supportive relationships, and effective stress management skills. The Section on Integrative Medicine hopes this clinical report serves as a catalyst for more open discussion of physician health and wellness within the AAP and will lead to the development of meaningful programs with the potential to benefit all AAP members.

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Promoting Education, Mentorship, and Support for Pediatric Research

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- *Policy Statement*

POLICY STATEMENT

Promoting Education, Mentorship, and Support for Pediatric Research

COMMITTEE ON PEDIATRIC RESEARCH

KEY WORDS

pediatric education, training, workforce, epidemiology, health services research, community-based participatory research, translational research, basic science research, postgraduate training

ABBREVIATIONS

NIH—National Institutes of Health

PBRN—practice-based research network

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abstract

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Pediatricians play a key role in advancing child health research to best attain and improve the physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. Child health presents unique issues that require investigators who specialize in pediatric research. In addition, the scope of the pediatric research enterprise is transdisciplinary and includes the full spectrum of basic science, translational, community-based, health services, and child health policy research. Although most pediatricians do not directly engage in research, knowledge of research methodologies and approaches promotes critical evaluation of scientific literature, the practice of evidence-based medicine, and advocacy for evidence-based child health policy. This statement includes specific recommendations to promote further research education and support at all levels of pediatric training, from premedical to continuing medical education, as well as recommendations to increase support and mentorship for research activities. Pediatric research is crucial to the American Academy of Pediatrics' goal of improving the health of all children. The American Academy of Pediatrics continues to promote and encourage efforts to facilitate the creation of new knowledge and ways to reduce barriers experienced by trainees, practitioners, and academic faculty pursuing research. *Pediatrics* 2014;133:943–949

INTRODUCTION

The goal of the American Academy of Pediatrics is the attainment of the optimal physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. To achieve this vision, pediatrics, as a field, must continually add to the current knowledge about how to best care for children through pediatric research. Research is broadly defined as the “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”¹ For the purposes of this statement, the term “child” health research refers to research focused on infants, children, adolescents, and young adults.

Child Health Research Is a Unique Field

Child health presents unique issues that require investigators who specialize in pediatric research. For example, childhood affects an

individual's long-term health trajectory and future adult outcomes, as many "adult" diseases have been shown to have their roots in childhood.²⁻⁴ The long-term effects of childhood interventions may be difficult to discern, and an intervention may take many years until any benefit is noted. Some cases, such as early child development interventions, can yield higher returns as a preventive measure compared with remedial services later in life⁵; however, it can be challenging to assess these potential long-term benefits with traditional approaches. Child health research also is characterized by the development and refinement of approaches to document long-term impact of early interventions.

The acceleration of racial and ethnic diversity in the United States is most pronounced in the pediatric population. Children now represent the most racially and ethnically diverse age group in the United States. As of 2011, most infants born in the United States had parents of ethnic minority groups.^{6,7} As a result, for those involved in child health care, it is crucial to develop and assess interventions to ensure they are culturally and linguistically, as well as developmentally, appropriate.^{8,9}

Compared with adults, children and adolescents have fewer common chronic conditions (eg, obesity, asthma, attention-deficit/hyperactivity disorder) but also have a wide plethora of rare diseases manifest in a very small percentage of children.^{10,11} It is challenging to develop research programs to study and create new treatments for rare and orphan disorders. This skewed epidemiology influences decisions regarding the allocation of resources of biomedical research.¹² For a variety of factors, medical advances are often developed for and tested initially in adults, frequently leaving pediatric

practitioners with little or no evidence-based guidance on appropriate use in children.¹³ The discovery, development, proper evidence-based evaluation, and translation of pediatric medical advances are vitally important to the health and well-being of the world's infants, children, adolescents, and young adults.

Finally, children are dependent on parents or adult guardians. This issue adds further ethical considerations in the conduct of pediatric research, such as the need to obtain parental consent and child or adolescent assent.^{14,15}

Child Health Research Is Broad in Scope

The scope of the pediatric research enterprise must also include the full spectrum of basic science, clinical, community-based, health policy, and health services research for appropriate translation into pediatric clinical practice. The Institute of Medicine¹² describes this translational research as the "transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods," as well as the "translation of the results of clinical studies into everyday clinical practice and health decision making." As a result, the research enterprise requires skills that include molecular and basic science laboratory skills; the conduct of randomized controlled trials and observational studies; and skills in designing, implementing, and evaluating interventions in everyday settings and/or analyzing the implications of health policies on child health outcomes.¹⁶ Furthermore, the movement of new knowledge is bidirectional, as insights gained in clinical settings inform inquiries in the basic sciences.

In the past, members of research teams focusing on pediatric issues had similar training; however, complex

clinical and societal issues require complementary sets of theoretical backgrounds and skills. Current issues in pediatric health are influenced by multiple factors (eg, genetic, environmental, political, social). Approaches to address these issues require medical research that involves a multitude of disciplines (eg, genetics, bioinformatics, epidemiology, sociology, health behavior and health education, health policy analysis, economics).¹⁷ In addition, research may need to acknowledge different theoretical models and incorporate diverse skills and methodologies used in other fields. Pediatric investigators may benefit from additional formal coursework, secondary degrees (eg, Master of Public Health, Doctor of Philosophy), research fellowships, and/or access to collaborators and faculty from other disciplines.

Working with families of patients in community settings through community-based participatory research adds a valuable dimension to health outside the treatment setting. Such research explores ways in which patient, family, and community priorities and settings may support or hinder complex disease management. Empowering the community as an equal partner in research offers promise for real change in the health of the population.¹⁸

The Importance of Pediatric Research Education for All Pediatricians

Although most pediatricians select careers primarily as practitioners, not research investigators,¹⁹ appropriate exposure to and an appreciation of research methodologies promotes skills and competencies for the critical evaluation of scientific literature and the practice of evidence-based medicine. These skills are closely interconnected to core competencies emphasized in pediatric education,

especially practice-based learning and improvement.²⁰ In addition, this training fosters a culture of deliberate and critical evaluation in pediatric clinical practice. It is not possible to practice evidence-based medicine without understanding the strengths and limitations of how the evidence was gathered and analyzed.²¹

In addition, a current gap is the paucity of child health research conducted in office-based settings, as opposed to highly specialized academic centers.²² Early exposure to research may increase the likelihood of practitioner involvement in practice-based research networks (PBRNs), which generate new knowledge that may be more generalizable to everyday practice.²³ Evidence-based practice is not possible without practice-based evidence. The increasing use of electronic health records in primary care settings and new maintenance-of-certification requirements create new opportunities and potential challenges for incorporating research in office settings. The generation of applicable, practice-based evidence is dependent on the active contributions of practicing pediatricians who understand and value pediatric research.

Current Threats to the Pediatric Research Enterprise

It is critical for pediatric research to continue to attract talented young trainees. Already, overall educational cost in comparison with potential future income is less favorable for physicians compared with many other professionals.²⁴ This situation is exacerbated for physician scientists, because they have more years of training, increased opportunity costs, and lower average salaries as academic pediatricians.²⁵ Over the past 3 decades, the amount of medical education debt has been increasing. In

2012, 86% of medical students obtained educational loans, with a resulting median individual medical student debt level of \$170 000.²⁶

The combination of increasing debt and lower expected earnings may discourage trainees from pursuing research careers.²⁷ In a survey of current pediatric subspecialist fellows, more than half indicated that, given the option, they would have chosen a shorter fellowship without a research requirement.²⁸ This sentiment was also noted by approximately 40% of junior faculty surveyed who had just completed fellowship training.²⁹ High levels of debt may contribute to a reluctance of young pediatricians to pursue a career in pediatric academic research and threaten the pipeline of future discoveries to benefit children.

In the past decade, extramural funding for research has become more competitive.³⁰ Pediatric funding from the National Institutes of Health (NIH) has mirrored the overall general NIH funding levels. As the budget for NIH has increased from fiscal year 1998 to fiscal year 2003 by 13.4%, pediatric funding increased by 11.5%; however, from fiscal year 2004 to fiscal year 2009, NIH appropriations increased by only 1.3%, with a corresponding change in pediatrics of only 0.3%. Accounting for inflation, the changes in the most recent period represent a negative change for pediatric research funding. Overall, for the individual pediatric investigator, this change represents few grants and fewer dollars per grant.³¹ There are fewer resources available to obtain a career development award and fewer resources for the transition to independent funding. In 2011, the average age of an investigator receiving an initial R01 (investigator-initiated grant) was 44 years for a Doctor of Medicine–Doctor of Philosophy

(MD-PhD) and 45 years for a Doctor of Medicine (MD).³² The decreased availability of research funding from NIH is a considerable barrier to young physician investigators.

Institutions may have a variety of expectations for faculty physician-researchers, such as teaching, clinical care, administration, and research.^{33,34} Given the increasingly competitive nature of securing extramural funding and requirements for clinical productivity, a career that attempts to balance research and clinical care is extremely challenging. Institutions need to invest significant resources (eg, senior faculty mentorship, space, technical support, supplies) as well as specified research time for junior faculty, which is often underestimated. This research time needs to be valued similarly to clinical, teaching, and administrative responsibilities.³⁵ In addition, it is important for clinical work to be synergistic with an investigator's research focus. Finally, extramural funding may not cover all project and infrastructure costs. As a result, institutional or medical center support may be necessary to support research faculty.

Diversity in the pediatric research workforce is increasingly important to help address the health care issues of a population that continues to grow more diverse.³⁶ Similar to the general pediatric workforce, there is a lack of diversity in academic pediatrics as well as among academic pediatric investigators.^{37–39} A lack of mentoring and support has been cited as one barrier to racial/ethnic minority application and competition for NIH research funding.⁴⁰ Examples of programs attempting to address this issue are the Academic Pediatric Association New Century Scholars Program and the Robert Wood Johnson

Foundation Harold Amos Medical Faculty Development Program.

RECOMMENDATIONS

The history of pediatric contributions to medical research is rich.⁴¹ These contributions are dependent on how pediatrics, as a field, promotes education, mentorship, and support for discovery and research throughout the career spectrum. As a result, education in research methodology should be provided, from medical school for pediatricians-in-training to continuing medical education for practicing pediatricians. The American Academy of Pediatrics continues to promote and encourage efforts to facilitate the creation of new knowledge and ways to reduce barriers experienced by trainees, practitioners, and academic faculty pursuing research.

Research Training Before Medical School

- Research training must begin early, ideally as a component of premedical course work.⁴²
- Early “pipeline” programs also may be helpful in attracting students of underrepresented minorities and lower socioeconomic status into the field of medicine and medical research. The pediatric research community should promote, encourage, and mentor high school and college students to develop career interests in medical research.

Research Training in Medical School

- Medical schools should provide a curriculum for health research.⁴³ This curriculum should encourage lifelong learning and develop trainee competencies in critically reviewing scientific literature. Fac-

ulty from pediatric departments should be encouraged to participate in the design and teaching of such curricula.

- Medical schools should consider recommending or requiring hypothesis-driven thesis projects for their students and should support dedicated time (for students and faculty), necessary resources, and faculty mentorship. Electives in research for credit (such as during the summer after the first and second years of medical school) or an additional year for fellowship for medical students to permit completion of a research project are additional options that can be established to support early development of the skills needed to conduct quality research.
- Medical student curriculum should include the issues of designing, conducting, and interpreting health research. The curriculum also should include the ethical dimensions of research, including informed consent, the role of institutional review boards, protection of research subjects, conflict of interest, and patient privacy, which are relevant to a research curriculum for physicians at any level of training or practice.

Research Training in Pediatric Residency Programs

- Consistent with the requirements of the Accreditation Council for Graduate Medical Education, an evidence-based medicine curriculum that can be integrated into a conference schedule should be developed for pediatric residents. The primary goal of this curriculum is to train pediatric resident competencies to evaluate and use medical literature as well as understand basic scientific methods, research design fundamentals, core

statistical principles, and the means to conduct critical literature reviews.

- Pediatric residency programs should promote research opportunities and encourage trainees to participate in a research project during their residency. Specified time, necessary resources, and faculty advisors are critical components in developing a research career or becoming involved in clinical research as a pediatric practitioner. These components should be readily available at all levels of pediatric training.

Research Training in Pediatric Fellowship Programs

- Fellowship programs should include advanced formal course work in research methodology that covers the widest possible spectrum of child health research. A research methodology curriculum for all fellowships in pediatrics should be developed that will outline the minimal core knowledge and skills expected of all child health researchers across subspecialties and general pediatrics. A core research methodology curriculum that is transdisciplinary and broad in scope can facilitate collaboration and potentially improve the quality and practical relevance of research conducted.
- The mentored-research experience is often cited as the key aspect of fellowship training.³³ Programs should assign all fellows to experienced faculty research preceptors with whom to work. To support mentorship, federal training grants should provide faculty mentor salary support in addition to trainee stipends. Institutions applying for fellowship training support should describe their plans for mentorship activities.

Research Training and Support for Junior Faculty

- Training and career development in a successful research career does not cease at the end of fellowship training. Junior faculty members require institutional support and mentoring to develop successful academic careers. Junior faculty members should develop individual career development plans and have such plans reviewed annually with their administrative and research mentors.
- Programs to identify, mentor, and link new investigators to a cohort of peers can help improve the likelihood of academic success.⁴⁴

Research Training Within Continuing Medical Education

- For continuing education of practitioners and academic faculty, educational institutions and professional organizations should establish programs in which intensive, brief training in research methodology or critical review of the scientific literature is provided.

Research and Pediatric Clinical Care

- Opportunities for pediatric practitioners to participate in research activities should be expanded through local and national PBRNs. Examples of national PBRNs include networks for outpatient settings (Pediatric Research in Office Settings), emergency department settings (the Pediatric Emergency Care Applied Research Network), and inpatient settings (Pediatric Research in Inpatient Settings), among others.
- PBRNs should be further promoted and expanded to reach practitioners previously underrepresented in these activities, especially those

who care for minority and underserved populations.⁴⁵

- To ensure that ongoing clinical experience can be harnessed to benefit future pediatric patients, incentives to support clinical research should be aligned with clinical care incentives.⁴⁶ Each clinical encounter represents a potential opportunity to contribute to primary data collection, quality improvement, or future secondary data analyses. An example of the successful integration of clinical care and clinical pediatric research is the Children's Oncology Group, which has improved the survival rate for childhood cancer through systematic, hypothesis-driven clinical research over the past 50 years.⁴⁷
 - Programs that help educate patients and families about the role, importance, and proper conduct of pediatric research should be promoted to help support the pediatric research enterprise.⁴⁸
- ### Loan Forgiveness and Research Support
- Programs that provide federal support for repayment of educational debt for physicians pursuing careers in child health research are important and should be continued to help encourage trainees to pursue careers in the field.⁴⁹
 - Secure and sustained resources need to be identified to cover costs of research education at all levels, including subsidizing faculty time, space, supplies, and equipment.
 - Professional organizations providing oversight for training of pediatricians and major federal funders of child health research (eg, NIH, Health Resources and Services Administration, and Agency for

Healthcare Research and Quality) should collect data to monitor the quality of pediatric research training, the number of pediatric researchers completing training and their productivity as researchers, and the level of support for child health research activities to ensure that there is ongoing progress in these areas.

- Junior faculty research success is dependent on outstanding mentorship from senior faculty. Academic institutions should support innovative programs to develop, cultivate, and recognize outstanding faculty research mentorship.⁵⁰

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Psychosocial Support for Youth Living With HIV

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- *Clinical Report*

CLINICAL REPORT

Psychosocial Support for Youth Living With HIV

abstract

FREE

This clinical report provides guidance for the pediatrician in addressing the psychosocial needs of adolescents and young adults living with HIV, which can improve linkage to care and adherence to life-saving antiretroviral (ARV) therapy. Recent national case surveillance data for youth (defined here as adolescents and young adults 13 to 24 years of age) revealed that the burden of HIV/AIDS fell most heavily and disproportionately on African American youth, particularly males having sex with males. To effectively increase linkage to care and sustain adherence to therapy, interventions should address the immediate drivers of ARV compliance and also address factors that provide broader social and structural support for HIV-infected adolescents and young adults. Interventions should address psychosocial development, including lack of future orientation, inadequate educational attainment and limited health literacy, failure to focus on the long-term consequences of near-term risk behaviors, and coping ability. Associated challenges are closely linked to the structural environment. Individual case management is essential to linkage to and retention in care, ARV adherence, and management of associated comorbidities. Integrating these skills into pediatric and adolescent HIV practice in a medical home setting is critical, given the alarming increase in new HIV infections in youth in the United States. *Pediatrics* 2014;133:558–562

BACKGROUND

The US government released a National Strategy for HIV/AIDS in 2010, in which 3 common goals were stated: (1) to reduce the number of individuals who become HIV infected; (2) to increase access to care and improve health outcomes in HIV-infected individuals; and (3) to reduce HIV-related health disparities.¹ These goals reflect significant progress in treatment of HIV infection with effective combination antiretroviral therapy (cART). This approach requires an ever-vigilant approach to long-term antiretroviral (ARV) adherence ($\geq 95\%$) for optimal virologic suppression and to offset the emergence of drug-resistant HIV so that future treatment options remain viable. Unfortunately many HIV-positive youth are not consistently linked into or retained in care. Youth who miss clinic appointments are more likely to develop life-threatening opportunistic infections. Poor adherence to cART is also associated with increased secondary HIV transmission.²

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KEY WORDS

HIV, pediatrics, youth, psychosocial support, antiretroviral therapy

ABBREVIATIONS

ARV—antiretroviral

cART—combination antiretroviral therapy

LGBT—lesbian, gay, bisexual, and transgender

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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Epidemiology

HIV-infected youth consist of 2 distinct populations: those who acquired HIV infection perinatally and those infected horizontally either by transfusion of blood products or by risk behaviors, including sexual activity and intravenous drug use. As of 2010, there were an estimated 10 797 perinatally HIV-infected people in the United States and dependent areas, and 76% of those affected were ≥ 13 years of age at the time of the analysis.³ Recent surveillance data from 2009 and 2010 reveal that youth account for 26% of all new HIV infections in the United States. Nearly 75% and 46% of the 12 200 new HIV infections in youth were attributable to males having sex with males and African American adolescents and young adults, respectively.⁴ Stigma, discrimination,⁵ infrequent condom use, alcohol and drug use, and having sex with older partners⁶ contributed to an even higher risk for acquiring HIV infection, disproportionately affecting minority youth residing in the south and the north-eastern United States. An estimated 60% of individuals were unaware of their underlying HIV infection.⁷

Challenges to ARV Adherence Among HIV-Infected Youth in the United States

Poor adherence to ARV therapy has been documented for both perinatally and horizontally HIV-infected youth. Many children infected with HIV perinatally have survived into their second or third decade of life with cART. However, during adolescence a number of psychological and social factors influence decision-making and create challenges for effective ARV adherence. A retrospective multicenter study of adolescents who acquired HIV perinatally reported that adolescents and young adults had the highest risk for resistance to available ARVs secondary to poor drug adherence.^{8,9} Similar

findings among adolescents and young adults who acquired HIV horizontally are reported, with as few as 24% in 1 study achieving virologic suppression at 3 years after initiation of cART.¹⁰ Such observations reinforce the need to design, implement, and evaluate strategies to increase and sustain adherence to therapy in this group. Interventions must factor the adolescents' stage of development, education level, health literacy and coping ability, and structural environment.¹¹ Factors that have been implicated in poor levels of adherence and ARV efficacy include poverty, inadequate food access,^{12,13} unstable housing,⁸ limited educational attainment, lack of stable employment, substance abuse, denial, stigma, homophobia, and discrimination.¹⁴

HIV Disclosure to Perinatally HIV-Infected Youth

As perinatally HIV-infected children approach adolescence, disclosure of their serostatus becomes essential for personal health maintenance and secondary HIV prevention. The first longitudinal study to examine the impact of disclosure of HIV status on health-related quality of life outcomes documented a median age at disclosure of 11 years. There were no significant changes over time in general health perception, psychological status, physical functioning, social/role functioning, or health care use domains. There was also no significant difference between time trends in quality of life scores before and after disclosure of HIV status, suggesting that diagnostic disclosure to children should not be delayed for fear of a negative impact on quality of life.¹⁵ Disclosure prior to sexual activity is also a public health issue affecting secondary HIV transmission.

Stigma and Disclosure in Horizontally HIV-Infected Youth

Horizontally HIV-infected youth have historically experienced rejection,

violence, and discrimination following disclosure of their HIV status. These experiences reflect prevalent societal stigma toward individuals who have acquired HIV through perceived risk behavior. The detrimental effect of HIV stigma on youth is often reported as more significant than the disease itself⁹ and negatively impacts ARV adherence. In one study, individuals who have HIV who reported high levels of HIV stigma were 3 times more likely to report problems with adherence.⁸ In contrast, when youth reported high levels of satisfaction with health care providers, this ameliorated the negative impact of stigma on adherence to treatment.¹⁶

Children and Youth Who Are in Foster Care or Homeless

Children who have HIV infection are often placed in foster care. Provision of medical services, including hospitalization, can be initially complicated by limited acquisition and communication of medical information. Eliminating barriers to sharing confidential information between medical providers, mental health case managers, and the foster care agency can improve care of the child or adolescent living with HIV.¹⁷ Institutional confidentiality and privacy policies guiding the care of HIV-infected youth should be developed.¹⁸ Samples of confidentiality policies can be found in *Bright Futures*.¹⁹ A complete medical history may be unavailable at the initial visit, and physicians must be prepared to document the circumstances surrounding the unavailability of previous medical records and provide service with limited knowledge of the youth's family, past medical or ARV history, or immunization status.²⁰

Studies indicate that youth aging out of foster care at 18 years of age and those who are lesbian, gay, bisexual, and transgender (LGBT) are especially susceptible to homelessness.²¹ The former, particularly minority youth,

have limited experience in independent living and lack the financial and social supports required to become independent.^{22,23} Many are at increased risk for sexual victimization, school dropout, substance abuse, and mental health comorbidities. Homeless adolescents and young adults frequently engage in prostitution in exchange for money, food, or shelter. The literature estimates that nightly in the United States, homeless youth can number between 1.6 and 2 million, including those living in shelters, on the streets, or in other temporary accommodations. Significantly, LGBT youth account for 20% to 40% of all homeless youth in the United States^{24–26} and are 6 to 12 times more likely to become HIV infected than other youth.²⁷ Homeless youth are 7 times as likely to die from AIDS and 16 times as likely to have HIV infection diagnosed as the general youth population.²⁶ These youth experience high rates of trauma and abuse before and during their experience of homelessness. Violence is reported in many forms, including physical (50%–82%), sexual (26%–39%), and family abuse (50%).²⁸

Acceptance of an HIV Diagnosis and Self-Disclosure to Others

Studies have revealed that youth who have chronic and/or terminal illness experience similar difficulty adjusting to their diagnosis, predominantly with medical management.^{29–32} However, HIV-infected youth have the unique difficulty of also living with stigma, which can interfere with their ability to adjust and cope.^{33,34} Significant stressors include acceptance of their diagnosis and rejection by others following disclosure.³⁵ Many fail to keep their medical appointments and present much later with opportunistic infections.

Schooling

Graduating from school is a major milestone for all youth. Youth living

with HIV infection are most concerned about disclosure to peers causing HIV stigmatization and adversely impacting social functioning. Youth living with HIV infection report changing grades after being given their diagnosis, with some ultimately dropping out of school. Like many youth who have chronic disease, HIV-infected youth in school have the added stress of skipping classes for medical appointments, which can negatively affect their grades.³⁵

THE RESPONSE TO IDENTIFIED PSYCHOSOCIAL NEEDS

1. Youth-Friendly Services

HIV Disclosure, Confidentiality, and Stigma

- (a) Confidentiality and privacy policies should be implemented. Given that homophobia, discrimination, and violence often affect HIV-positive LGBT adolescents and young adults, better outcomes are reported in health care settings where there are confidentiality and privacy policies that are discussed during enrollment and at subsequent clinic visits.^{18,36,37} Standard forms for and policies on confidentiality as well as policies on privacy for youth are available and can be modified as state or local jurisdictions legally permit.³⁸
- (b) HIV stigma should be addressed within a developmentally appropriate unit offering comprehensive medical services like a medical home,¹⁶ with patients engaged in trusting relationships with health care providers and being kept well informed of the status of their illness.^{16,39}

Denial and Coping With the Diagnosis of HIV Infection

- (c) Services should address how youth can cope with their HIV

diagnosis. Infrastructure in the medical home that promotes coping through family, peer groups, and spiritual groups as well as professional involvement can improve adherence to clinic appointments and ARV therapy.¹⁶

Case Management and Multidisciplinary Care in the Medical Home

- (d) The sole provision of medical treatment is not sufficient to engage and retain HIV-infected youth in care. Service models that include consideration of gender, race and ethnicity, developmental stage, mental health, family composition, peer reference groups and relationships, economic resources, sexuality, and sexual behaviors are more likely to improve outcomes.⁴⁰
- (e) Effective medical treatment should be inclusive of flexible scheduling and a multidisciplinary team approach that includes aggressive case management and care coordination.^{41,42}
- (f) Patients should be assigned to a physician-led medical home team that can regularly provide all of the medical services and continuity of care.⁴¹
- (g) Medical care services should facilitate prompt access to mental health services.
- (h) Regular multidisciplinary team meetings should be scheduled to include all providers involved in the patient's care.

2. Structural Program Elements

- (a) Addressing barriers to health care use may assist youth in improving disease self-management. Perceived needs in 1 study of 107 HIV-infected youth included access to mental health services (45%), alcohol and drug treatment (14%), transportation to health care

settings (40%), and housing (47%). Youth who expressed these needs were unable or unwilling to “focus on accessing” HIV comprehensive health care.^{41,43}

- (b) Youth buddies are peer advocates who conduct peer-to-peer counseling. When youth buddies are used as part of the comprehensive medical services team, they can be effective in engaging and retaining youth in care.⁴¹

3. Social Media

Health Insurance Portability and Accountability Act-compliant secure messaging through the Internet, mobile phones, and social media can be used for improving appointment and medication adherence. Almost all adolescents and young adults have used the Internet

and mobile phones in their daily lives.⁴⁴ Ninety-five percent of youth report using the Internet and are avid users of social media, with 90% of 13- to 17-year-olds reporting its use, 80% reporting a current profile on a social network site, and 22% having a Twitter account.^{45–50}

4. Advocacy

Pediatricians should advocate for resources that are necessary to provide optimal care for HIV-infected adolescents and young adults to include social support, rehabilitation, education, and access to basic necessities, including stable housing, without which the best medical care may prove ineffective. Pediatricians can advocate at the community and legislative/public policy levels (<http://www.aap.org/en-us/advocacy-and-policy/Pages/Advocacy-and-Policy.aspx>).

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Recommendations for Prevention and Control of Influenza in Children, 2014–2015

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- *Policy Statement*

- *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



POLICY STATEMENT

Recommendations for Prevention and Control of Influenza in Children, 2014–2015

COMMITTEE ON INFECTIOUS DISEASES

KEY WORDS

influenza, immunization, live attenuated influenza vaccine, inactivated influenza vaccine, vaccine, children, pediatrics

ABBREVIATIONS

AAP—American Academy of Pediatrics
 ccIV3—trivalent cell culture-based inactivated influenza vaccine
 CDC—Centers for Disease Control and Prevention
 FDA—US Food and Drug Administration
 GRADE—Grading of Recommendations Assessment, Development, and Evaluation
 HCP—health care personnel
 ID—intradermal
 IIV—inactivated influenza vaccine
 IIV3—trivalent inactivated influenza vaccine
 IIV4—quadrivalent inactivated influenza vaccine
 IM—intramuscular
 LAIV—live attenuated influenza vaccine
 LAIV4—quadrivalent live attenuated influenza vaccine
 NAIs—neuraminidase inhibitors
 PCR—polymerase chain reaction
 PCV13—13-valent pneumococcal conjugate vaccine
 pH1N1—influenza A (H1N1) pandemic virus
 RIV3—trivalent recombinant influenza vaccine

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The guidance in this policy statement does not indicate an exclusive course of treatment or serve as a standard of care. Variations, taking into account individual circumstances, may be appropriate.

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(Continued on last page)

abstract

FREE

The purpose of this statement is to update recommendations for routine use of seasonal influenza vaccine and antiviral medications for the prevention and treatment of influenza in children. The American Academy of Pediatrics recommends annual seasonal influenza immunization for *all* people 6 months and older, including all children and adolescents. Highlights for the upcoming 2014–2015 season include the following:

1. The influenza vaccine composition for the 2014–2015 season is *unchanged* from the 2013–2014 season.
2. Both trivalent and quadrivalent influenza vaccines are available in the United States for the 2014–2015 season.
3. Annual universal influenza immunization is indicated with either a trivalent or quadrivalent vaccine (no preference).
4. Live attenuated influenza vaccine (LAIV) should be considered for *healthy* children 2 through 8 years of age who have no contraindications or precautions to the intranasal vaccine. If LAIV is not readily available, inactivated influenza vaccine (IIV) should be used; vaccination should not be delayed to obtain LAIV.
5. The dosing algorithm for administration of influenza vaccine to children 6 months through 8 years of age reflects that virus strains in the vaccine have not changed from last season.

As always, pediatricians, nurses, and all other health care personnel should be immunized themselves and should promote influenza vaccine use and infection control measures. In addition, pediatricians should promptly identify clinical influenza infections to enable rapid antiviral treatment, when indicated, to reduce morbidity and mortality. *Pediatrics* 2014;134:e1503–e1519

INTRODUCTION

The American Academy of Pediatrics (AAP) recommends annual seasonal influenza immunization for *all* people 6 months and older, including all children and adolescents, during the 2014–2015 influenza season. In addition, special effort should be made to vaccinate people in the following groups:

- All children, including infants born preterm, who are 6 months and older with conditions that increase the risk of complications from influenza (eg, children with chronic medical conditions, such as asthma, diabetes mellitus, hemodynamically significant cardiac disease, immunosuppression, or neurologic and neurodevelopmental disorders);
- Children of American Indian or Alaska Native heritage
- All household contacts and out-of-home care providers of
 - Children with high-risk conditions
 - Children younger than 5 years, especially infants younger than 6 months
- All health care personnel (HCP)
- All child care providers and staff
- All women who are pregnant, are considering pregnancy, are in the postpartum period, or are breastfeeding during the influenza season

KEY POINTS RELEVANT FOR THE 2014–2015 INFLUENZA SEASON

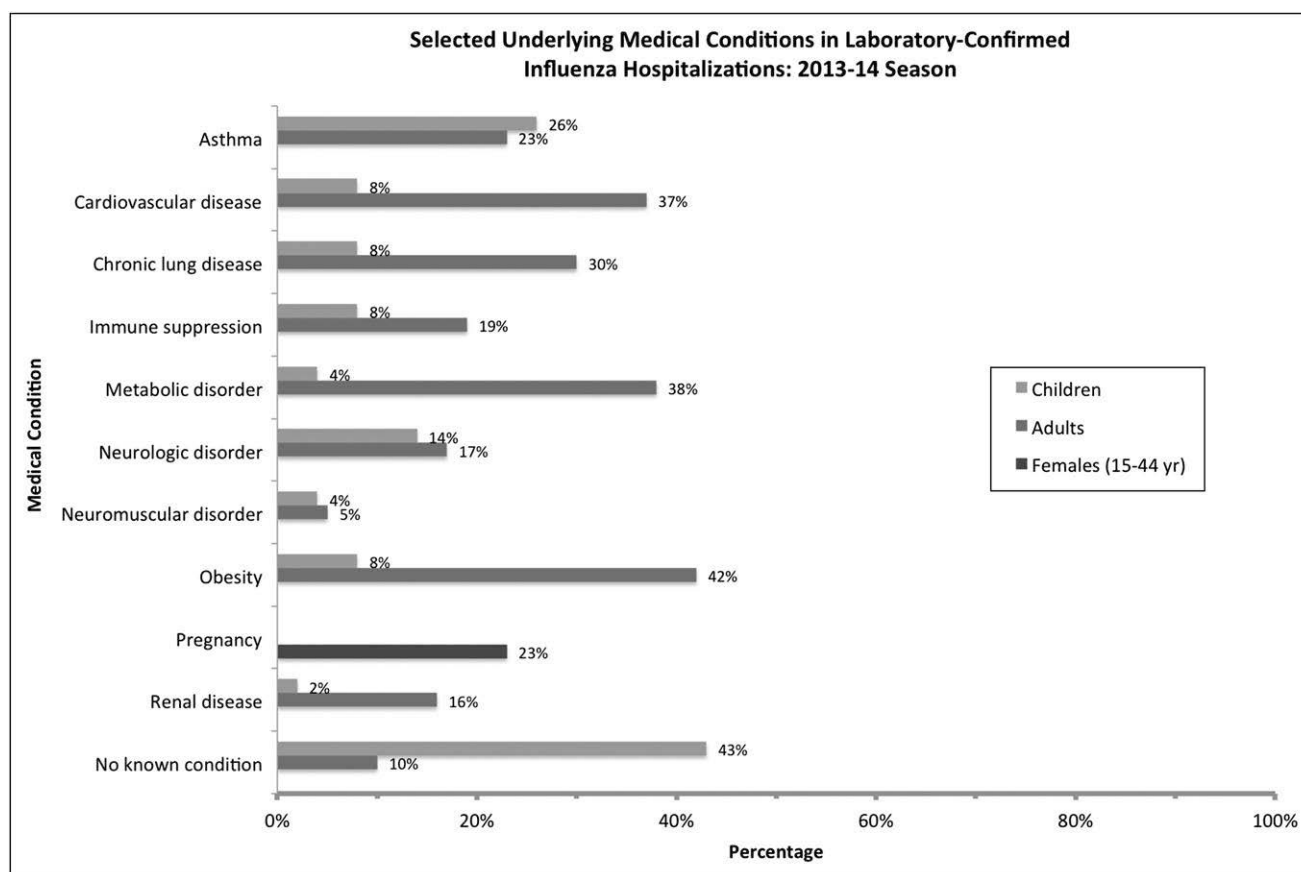
1. **Annual seasonal influenza vaccine is recommended for all people 6 months and older, including all children and adolescents, during the 2014–2015 influenza season.** It is important that household contacts and out-of-home care providers of children younger than 5 years, especially infants younger than 6 months, and children of any age at high risk of complications from influenza (eg, children with chronic medical conditions, such as asthma, diabetes mellitus, hemodynamically significant cardiac disease, immunosuppression, or neurologic and neurodevelopmental disorders) receive annual influenza vaccine. In the United States,

more than two-thirds of children younger than 6 years and almost all children 6 years and older spend significant time in child care or school settings outside the home. Exposure to groups of children increases the risk of contracting infectious diseases. Children younger than 2 years are at elevated risk of hospitalization and complications attributable to influenza. School-aged children bear a large influenza disease burden and have a significantly higher chance of seeking influenza-related medical care compared with healthy adults. Reducing influenza virus transmission (eg, appropriate hand hygiene, respiratory hygiene/cough etiquette) among children who attend out-of-home child care or school has been shown to decrease the burden of childhood influenza and transmission of influenza virus to household contacts and community members of all ages.

2. The percentage of outpatient visits for influenza-like illness, rates of hospitalization, and deaths attributed to pneumonia and influenza were lower during the 2013–2014 influenza season when compared with the previous season. As of August 23, 2014, 107 laboratory-confirmed influenza-associated pediatric deaths were reported to the Centers for Disease Control and Prevention (CDC) during the 2013–2014 influenza season. The 2009 influenza A (H1N1) pandemic (pH1N1) viruses predominated, but influenza A (H3N2) and influenza B viruses also were reported in the United States. Of the 107 deaths, 87 were associated with influenza A viruses, and 16 deaths were associated with influenza B viruses. Two deaths were associated with an undetermined type of influenza

virus, and 2 deaths were associated with dual infection with both influenza A and B viruses. Although children with certain conditions are at higher risk of complications, 47% of the deaths occurred in children with no high-risk underlying medical condition. Among children hospitalized with influenza and for whom medical chart data were available, approximately 43% had no recorded underlying condition, whereas 26% had underlying asthma or reactive airway disease (Fig 1). A recent preliminary observation of the 2013–2014 influenza season noted a high number of healthy people (ranging from infants to older adults) who needed care in the ICU, 91% of whom were not previously vaccinated.

3. Both trivalent and quadrivalent influenza vaccines are available in the United States for the 2014–2015 season. Neither vaccine formulation is preferred over the other. Both vaccines contain an A/California/7/2009 (H1N1)–like virus, an A/Texas/50/2012 (H3N2) virus, and a B/Massachusetts/2/2012–like virus (B/Yamagata lineage). The quadrivalent influenza vaccines include an additional B virus (B/Brisbane/60/2008–like virus [B/Victoria lineage]). These strains are unchanged from those in the 2013–2014 seasonal influenza vaccines.
4. Optimal protection is achieved through annual immunization. Antibody titers wane to 50% of their original levels 6 to 12 months after vaccination. Although the vaccine strains for the 2014–2015 season are unchanged from last season, a repeat dose this season is critical for maintaining protection in all populations.
5. Using the Grading of Recommendations Assessment, Development,

**FIGURE 1**

Selected underlying medical conditions in patients hospitalized with laboratory-confirmed influenza, FluSurv-NET 2013–2014. Source: Centers for Disease Control and Prevention. FluView 2013–2014 Preliminary Data as of August 23, 2014. Available at: <http://gis.cdc.gov/grasp/fluview/FluHospChars.html>. Asthma includes a medical diagnosis of asthma or reactive airway disease. Cardiovascular diseases include conditions such as coronary heart disease, cardiac valve disorders, congestive heart failure, pulmonary hypertension, and aortic stenosis; does not include hypertension disease only. Chronic lung diseases include conditions such as chronic obstructive pulmonary disease, bronchiolitis obliterans, chronic aspiration pneumonia, and interstitial lung disease. Immune suppression includes conditions such as immunoglobulin deficiency, leukemia, lymphoma, HIV/AIDS, and the use of immunosuppressive medications. Metabolic disorders include conditions such as diabetes mellitus, thyroid dysfunction, adrenal insufficiency, and liver disease. Neurologic disorders include conditions such as seizure disorders, cerebral palsy, and cognitive dysfunction. Neuromuscular disorders include conditions such as multiple sclerosis and muscular dystrophy. Obesity was assigned if indicated in patient's medical chart or if BMI >30 kg/m². Pregnancy percentage calculated by using number of female cases aged between 15 and 44 years of age as the denominator. Renal diseases include conditions such as acute or chronic renal failure, nephrotic syndrome, glomerulonephritis, and impaired creatinine clearance. No known condition indicates that the case did not have any known underlying medical condition indicated in medical chart at the time of hospitalization.

and Evaluation (GRADE) framework, the CDC Advisory Committee on Immunization Practices (ACIP) systematically reviewed the evidence pertaining to the efficacy of live attenuated influenza vaccine (LAIV) and inactivated influenza vaccine (IIV) for healthy children. It concluded that there is greater relative efficacy of LAIV as compared with IIV against laboratory-confirmed influenza among younger children (based on 2 studies including children up to 6 years of

age). The risk of adverse events after immunization, including fever, wheezing, and serious adverse events, appears to be similar for LAIV and IIV. Therefore, LAIV should be considered for *healthy* children 2 through 8 years of age who have no contraindications or precautions to the intranasal vaccine. If LAIV is not readily available, IIV should be used; vaccination should not be delayed to obtain LAIV. The age of 8 years is selected as the upper limit for this recommenda-

tion on the basis of demonstration of superior efficacy of LAIV (ages 2 through 6 years) and for programmatic consistency (8 years is the upper age limit for receipt of 2 doses of influenza vaccine in a previously unvaccinated child).

6. The number of seasonal influenza vaccine doses to be administered in the 2014–2015 influenza season depends on the child's age at the time of the first administered dose and his or her vaccine history (Fig 2):

- Influenza vaccines are not licensed for administration to infants younger than 6 months.
- Children 9 years and older need only 1 dose.
- Children 6 months through 8 years of age receiving the seasonal influenza vaccine *for the first time* should receive a second dose this season at least 4 weeks after the first dose.
- Children 6 months through 8 years of age need only 1 dose of vaccine in 2014–2015 if they have received it according to any of the following scenarios:
 - ✓ At least 1 dose of 2013–2014 seasonal influenza vaccine.
 - ✓ 2 or more doses of seasonal vaccine since July 1, 2010.
 - ✓ 2 or more doses of seasonal influenza vaccine from any previous season and at least 1 clearly documented dose of a pH1N1-containing vaccine (ie, any seasonal vaccine since July 1, 2010 or a monovalent pH1N1 vaccine during the 2009–2010 season).

Children in this age group for whom one of these conditions is not met need 2 doses in 2014–2015 to be adequately primed. Vaccination should not be delayed to obtain a specific product for either dose. Any available, age-appropriate trivalent or quadrivalent vaccine can be used; IIV and LAIV are considered interchangeable. A child who receives only 1 of the 2 doses as a quadrivalent formulation is likely to be less primed against the additional B virus.

7. Pediatric offices may choose to serve as an alternative venue for

providing influenza immunization for parents and other care providers of children if the practice is acceptable to both pediatricians and the adults who are to be vaccinated.¹ There are important medical liability issues and medical record documentation requirements that must be addressed before a pediatrician begins immunizing adults (see details at www.aapredbook.org/implementation). Pediatricians are reminded to document the recommendation for adult immunization in the vulnerable child's medical record. In addition, adults should still be encouraged to have a medical home and communicate their immunization status to their primary care provider. Offering immunizations in the pediatric practice setting would not be intended to undermine the adult medical home model but could serve as an additional venue for parents and other care providers for children to receive vaccinations. Immunization of close contacts of children at high risk of influenza-related complications is intended to reduce their risk of contagion (ie, "cocooning"). The practice of cocooning may help protect infants younger than 6 months, because they are too young to be immunized with influenza vaccine. Infants younger than 6 months also can be protected through vaccination of their mothers during pregnancy, with resulting transplacental transfer of antibodies. The risk of influenza-associated hospitalization in healthy children younger than 24 months has been shown to be greater than the risk of hospitalization in previously recognized high-risk groups, such as older adults, during influenza season. Children 24 through 59 months of age have

shown higher rates of outpatient visits and antimicrobial use associated with influenza-like illnesses than older children.

8. As soon as the seasonal influenza vaccine is available locally, pediatricians or vaccine administrators should immunize HCP, notify parents and caregivers of vaccine availability and the importance of annual vaccination, and immunize children 6 months and older per recommendations, especially those at high risk of complications from influenza. Health care provider endorsement plays a major role in vaccine uptake. A strong correlation exists between health care provider endorsement of influenza vaccine and patient acceptance. Prompt initiation of influenza immunization and continuance of immunization throughout the influenza season, whether or not influenza is circulating (or has circulated) in the community, are critical components of an effective immunization strategy. Administering the vaccine early during the influenza season is not believed to pose a significant risk that immunity might wane before the end of the season. The seasonal vaccine is not 100% effective, but it still is the best strategy available for preventing illness from influenza. It is moderately effective in reducing the risk for outpatient medical visits caused by circulating influenza viruses by approximately one-half to three-quarters in most people. Even during seasons when the vaccine is only moderately effective, influenza vaccine has been shown to reduce illness, antibiotic use, doctor visits, time lost from work, hospitalizations, and deaths.
9. Providers should continue to offer vaccine until the vaccine expiration

Number of 2014–2015 Seasonal Influenza Vaccine Doses for Children 6 Months Through 8 Years of Age

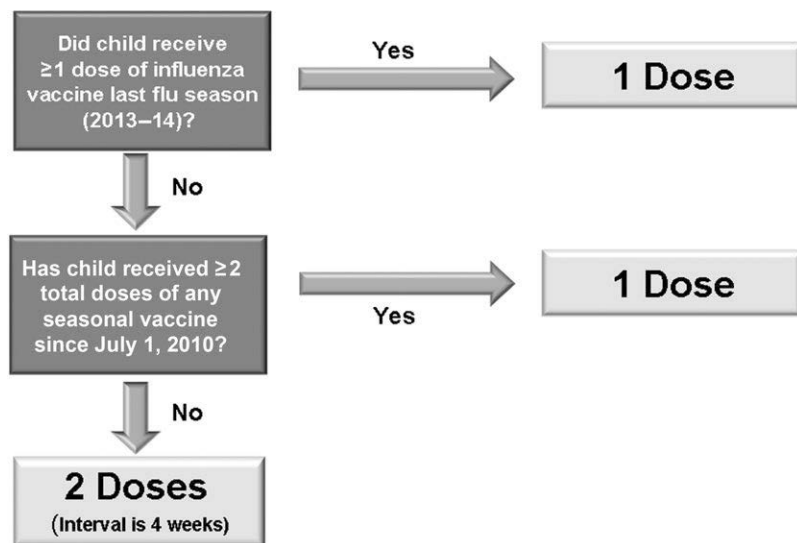


FIGURE 2

Number of 2014–2015 seasonal influenza vaccine doses for children 6 months through 8 years of age. For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010 is available, if a child aged 6 months through 8 years is known to have received 2 or more doses of seasonal influenza vaccine from any previous season *and* at least 1 clearly documented dose of a pH1N1-containing vaccine (ie, any seasonal vaccine since July 1, 2010 or a monovalent pH1N1 vaccine during the 2009–2010 season), then the child needs only 1 dose for 2014–2015.

date (June 30, marking the end of the influenza season), because influenza is unpredictable. Protective immune responses persist throughout the influenza season, which can have >1 disease peak and may extend into March or later. Although the peak of influenza activity in the United States tends to occur in January through March, influenza activity can occur in early fall (ie, October and November) or late spring (eg, influenza circulated through the end of May during the 2013–2014 season). This approach also provides ample opportunity to administer a second dose of vaccine when indicated, as detailed in Key Point 6 above. In addition, international travel may result in potential exposure to influenza throughout the year.

10. HCP, influenza campaign organizers, and public health agencies

should collaborate to develop improved strategies for planning, communication, and administration of vaccines.

- Plan to make seasonal influenza vaccine easily accessible for all children. Examples include alerts to families that vaccine is available (eg, e-mails, texts, and patient portals); creating walk-in influenza clinics; extending hours beyond routine times during peak vaccination periods; administering influenza vaccine during both well and sick visits; considering how to immunize parents, adult caregivers, and siblings at the same time in the same office setting as children¹; and working with other institutions (eg, schools, child care programs, and religious organizations) or alter-

native care sites, such as emergency departments, to expand venues for administering vaccine. If a child or adult receives influenza vaccine outside his or her medical home, such as at a pharmacy, retail-based clinic, or another practice, appropriate documentation of immunization should be provided to the patient for his or her medical home and entered into the state immunization registry where possible.

- Concerted efforts among the aforementioned groups, plus vaccine manufacturers, distributors, and payers, also are necessary to prioritize distribution appropriately to the primary care office setting and patient-centered medical home before other venues, especially when vaccine supplies are delayed or limited.
 - Vaccine safety, effectiveness, and indications must be communicated properly to the public. Pediatricians and office staff should explain the importance of annual influenza vaccination for children and emphasize when a second dose of vaccine is indicated. HCP should act as role models by receiving influenza immunization annually and recommending annual immunizations to both colleagues and patients. Influenza immunization programs for HCP benefit the health of employees, their patients, and members of the community.²
11. Antiviral medications also are important in the control of influenza but are not a substitute for influenza immunization. The neuraminidase inhibitors (NAIs) oral oseltamivir (Tamiflu; Roche Laboratories, Nutley, NJ) and inhaled

zanamivir (Relenza; GlaxoSmithKline, Research Triangle Park, NC) are the only antiviral medications recommended for chemoprophylaxis or treatment of influenza during the 2014–2015 season. Intravenous preparations of oseltamivir, zanamivir, and peramivir are not approved by the US Food and Drug Administration (FDA). However, in consultation with infectious diseases specialists, investigational intravenous zanamivir should be considered for critically ill children, especially those who are immunocompromised or cannot tolerate or absorb oral or enterically administered oseltamivir. Recent viral surveillance and resistance data indicate that the majority of currently circulating influenza viruses likely to cause 2014–2015 seasonal influenza in North America continue to be sensitive to oseltamivir and zanamivir. In contrast, amantadine and rimantadine should not be used, because circulating influenza A viruses currently have levels of resistance to these drugs, and they are not effective against influenza B viruses. Because resistance characteristics can change rapidly, pediatricians should verify susceptibility data at the start of the influenza season and monitor them throughout the season. Up-to-date information can be found on the AAP Web site (www.aap.org or www.aapredbook.org/flu), through state-specific AAP chapter Web sites, or on the CDC Web site (www.cdc.gov/flu/index.htm).

SEASONAL INFLUENZA VACCINES

Before the 2013–2014 influenza season, only trivalent influenza vaccines that included a single influenza B strain were available. However, since 1985, 2 antigenically distinct lineages (ie, Victoria or Yamagata) of influenza

B viruses have circulated globally. Vaccination against 1 B viral lineage confers little cross-protection against the other B viral lineage. Thus, trivalent vaccines offer limited immunity against circulating influenza B strains of the lineage not present in the vaccine. Furthermore, in recent years it has proven difficult to predict consistently which B lineage will predominate during a given influenza season. Therefore, a quadrivalent influenza vaccine with influenza B strains of *both* lineages should offer greater protection. Post-marketing safety and vaccine effectiveness data are not yet available, precluding a full risk–benefit analysis of newer versus previously available products.

For the 2014–2015 season, IIVs will be available for intramuscular (IM) injection in both trivalent (IIV3) and quadrivalent (IIV4) formulations. The intranasally administered LAIV will be available only in a quadrivalent formulation (LAIV4). All quadrivalent vaccines will contain the identical influenza strains anticipated to circulate during the 2014–2015 influenza season.

IIVs contain no live virus. IIV3 formulations are available for IM and intradermal (ID) use. The IM formulation of IIV3 is licensed and recommended for children 6 months and older and adults, including people with and without chronic medical conditions. The most common adverse events after IIV administration are local injection site pain and tenderness. Fever may occur within 24 hours after immunization in approximately 10% to 35% of children younger than 2 years but rarely in older children and adults. Mild systemic symptoms, such as nausea, lethargy, headache, muscle aches, and chills, may occur after administration of IIV3.

An ID formulation of IIV3 is licensed for use in people 18 through 64 years of age. ID vaccine administration involves

a microinjection with a shorter needle than needles used for IM administration. The most common adverse events are redness, induration, swelling, pain, and itching, which occur at the site of administration; although all adverse events occur at a slightly higher rate with the IM formulation of IIV3, the rate of pain was similar between ID and IM. Headache, myalgia, and malaise may occur and tend to occur at the same rate as that with the IM formulation of IIV3. There is no preference for IM or ID immunization with IIV3 in people 18 years or older. Therefore, pediatricians may choose to use either the IM or ID product for their young adult patients and for any adults they are vaccinating (ie, as part of a cocooning strategy).

IIV4 is available in IM but not ID formulations. One formulation of IIV4 is licensed for use in children as young as 6 months of age. In children, the most common injection site adverse reactions were pain, redness, and swelling. The most common systemic adverse events were drowsiness, irritability, loss of appetite, fatigue, muscle aches, headache, arthralgia, and gastrointestinal tract symptoms. These events were reported with comparable frequency among participants receiving the licensed comparator trivalent vaccines. IIV4 is an acceptable vaccine for people 6 months or older when otherwise appropriate and may offer broader protection than IIV3. The relative quantity of doses of IIV4 that will be available is not certain and likely to be limited.

During the 2 influenza seasons spanning 2010–2012, there were increased reports of febrile seizures in the United States in young children who received IIV and the 13-valent pneumococcal conjugate vaccine (PCV13) concomitantly, but this has not been observed in more recent seasons. Simultaneous administration of IIV and

PCV13 for the 2014–2015 influenza season continues to be recommended when both vaccines are indicated.

LAIV4 is a quadrivalent live attenuated influenza vaccine that is administered intranasally. It is licensed by the FDA for previously healthy people 2 through 49 years of age. The most commonly reported reactions in children were runny nose or nasal congestion, headache, decreased activity or lethargy, and sore throat. LAIV4 should not be administered to people with notable nasal congestion that would impede vaccine delivery. The safety of LAIV in people with a history of asthma, diabetes mellitus, or other high-risk medical conditions associated with an elevated risk of complications from influenza (see Contraindications and Precautions) has not been established. In a postlicensure surveillance of LAIV over 7 seasons, the Vaccine Adverse Event Reporting System (VAERS), jointly sponsored by the FDA and CDC, did not identify any new or unexpected safety concerns, although there were reports of use of LAIV in people with a contraindication or precaution. The use of LAIV in young children with chronic medical conditions, including asthma, has been implemented outside the United States, but the vaccine is not licensed for these indications in the United States.

Two trivalent influenza vaccines manufactured using technologies that do not use eggs will also be available for people 18 years or older during the 2014–2015 season: cell culture–based inactivated influenza vaccine (ccIIV3) and recombinant influenza vaccine (RIV3). These manufacturing methods would probably permit a more rapid scale-up of vaccine production when needed, such as during a pandemic.

ccIIV3 is a trivalent cell culture–based inactivated influenza vaccine indicated for people 18 years or older, administered as an IM injection. ccIIV3 has comparable immunogenicity to US-

licensed IIV3 comparator vaccines. Although ccIIV3 is manufactured from virus propagated in Madin Darby canine kidney cells rather than embryonated eggs, before production, seed virus is created from the World Health Organization reference virus strains, which have been passaged in eggs. However, egg protein is not detectable in the final vaccine, and egg allergy is not mentioned as a contraindication in the package insert. Other contraindications to vaccine delivery are similar to those for other IIVs. The most common solicited adverse reactions included injection site pain, erythema at the injection site, headache, fatigue, myalgia, and malaise.

RIV3 is a recombinant baculovirus–expressed hemagglutinin vaccine produced in cell culture. It is indicated for people 18 through 49 years of age and is administered via IM injection. The most frequently reported adverse events were pain, headache, myalgia, and fatigue. There are no egg proteins in this version of influenza vaccine.

Tables 1 and 2 summarize information on the types of 2014–2015 seasonal influenza vaccines licensed for immunization of children and adults. It is likely that more than 1 type or brand of vaccine may be appropriate for vaccine recipients. However, vaccination should not be delayed to obtain a specific product.

A large body of scientific evidence demonstrates that thimerosal-containing vaccines are not associated with elevated risk of autism spectrum disorders in children. Therefore, the AAP extends its strongest support to the recent World Health Organization recommendations to retain the use of thimerosal in the global vaccine supply. Some people may still raise concerns about the minute amounts of thimerosal in IIV vaccines, and in some states there is a legislated restriction on the use of thimerosal-containing vaccines.

The benefits of protecting children against the known risks of influenza are clear. Therefore, children should receive any available formulation of IIV rather than delaying immunization while waiting for reduced thimerosal-content or thimerosal-free vaccines. Although some formulations of IIV contain only a trace amount of thimerosal, certain types can be obtained thimerosal free. LAIV4 does not contain thimerosal. Vaccine manufacturers are delivering increasing amounts of thimerosal-free influenza vaccine each year.

INFLUENZA VACCINES AND EGG ALLERGY

Although most IIV and LAIV vaccines are produced in eggs and contain measurable amounts of egg protein, recent data have shown that IIV administered in a single, age-appropriate dose is well tolerated by most recipients with a history of egg allergy. More conservative approaches in children with a history of egg allergy, such as skin testing or a 2-step graded challenge, no longer are recommended. No data have been published on the safety of administering LAIV to egg-allergic recipients.

As a precaution, pediatricians should continue to determine whether the presumed egg allergy is based on a mild (ie, hives alone) or severe reaction (ie, anaphylaxis involving cardiovascular changes, respiratory or gastrointestinal tract symptoms, or reactions that necessitate the use of epinephrine). Pediatricians should consult with an allergist for children with a history of severe reaction. Most vaccine administration to patients with egg allergy can occur without the need for referral. Data indicate that only approximately 1% of children have immunoglobulin E–mediated sensitivity to egg, and of those, a rare minority have a severe allergy. The Joint Task Force on Practice Parameters,

TABLE 1 Recommended Seasonal Influenza Vaccines for Different Age Groups: United States, 2014–2015 Influenza Season

Vaccine	Trade Name	Manufacturer	Presentation	Thimerosal Mercury Content (µg of Hg per 0.5-mL dose)	Age Group
Inactivated					
IIV3	Fluzone	Sanofi Pasteur	0.25-mL prefilled syringe	0	6–35 mo
			0.5-mL prefilled syringe	0	≥36 mo
			0.5-mL vial	0	≥36 mo
			5.0-mL multidose vial	25	≥6 mo
IIV3	Fluzone Intradermal	Sanofi Pasteur	0.1-mL prefilled microinjection	0	18–64 y
IIV3	Fluzone HD	Sanofi Pasteur	0.5-mL prefilled syringe	0	≥65 y
IIV3	Fluvirin	Novartis	0.5-mL prefilled syringe	≤1.0	≥4 y
			5.0-mL multidose vial	25	≥4 y
			0.5-mL prefilled syringe	0	≥36 mo
IIV3	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0-mL multidose vial	25	≥36 mo
IIV3	Afluria	bioCSL	0.5-mL prefilled syringe	0	≥9 y ^a
			5-mL multidose vial	24.5	≥9 y ^a
cclIV3	Flucelvax	Novartis Vaccines	0.5-mL prefilled syringe	0	≥18 y
IIV4	Fluzone Quadrivalent	Sanofi Pasteur	0.25-mL prefilled syringe	0	6–35 mo
			0.5-mL prefilled syringe	0	≥36 mo
			0.5-mL vial	0	≥36 mo
IIV4	Fluarix Quadrivalent	GlaxoSmithKline	0.5-mL prefilled syringe	0	≥36 mo
IIV4	FluLaval Quadrivalent	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0-mL multidose vial	25	≥36 mo
Recombinant					
RIV3	FluBlok	Protein Sciences	0.5-mL vial	0	18–49y
Live attenuated					
LAIV4	FluMist Quadrivalent	MedImmune	0.2-mL sprayer	0	2–49 y

Sources: American Academy of Pediatrics, Committee on Infectious Diseases. Recommendations for prevention and control of influenza in children, 2013–2014. *Pediatrics*. 2013;132(4):e1089–e1104; and Centers for Disease Control and Prevention. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2014–2015 influenza season. *MMWR Recomm Rep*. 2014;63(32):691–697.

^a Age indication per package insert is ≥5 y; however, the Advisory Committee on Immunization Practices recommends Afluria not be used in children 6 mo through 8 y of age because of febrile reactions reported in this age group. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child 5 through 8 y of age who has a medical condition that increases the child's risk of influenza complications, Afluria can be used; however, pediatricians should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine.

representing the American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma & Immunology (ACAAI), recently published an updated recommendation that special precautions regarding medical setting and waiting periods after administration of IIV to egg-allergic recipients beyond those recommended for any vaccine are not warranted. This concept has not been universally accepted by all allergists, so the AAP recommendation has not changed.

Standard immunization practice should include the ability to respond to acute hypersensitivity reactions. Therefore, influenza vaccine should be given to children with egg allergy with the following preconditions (Fig 3):

- Appropriate resuscitative equipment must be readily available.³
- The vaccine recipient should be observed in the office for 30 minutes after immunization, the usual observation time for receiving immunotherapy.

Providers may consider use of cclIV3 or RIV3 vaccines produced via non-egg-based technologies for patients 18 years or older with egg allergy in settings in which these vaccines are available and otherwise age appropriate. cclIV3, which does contain trace amounts of ovalbumin, should be administered according to the guidance for other IIVs (Fig 3). RIV3, which contains no ovalbumin, may be administered to people with egg allergy of any

severity who are 18 through 49 years of age and do not have other contraindications. However, vaccination of patients with mild egg allergy should not be delayed if RIV3 or cclIV3 is not available. Instead, any licensed, age-appropriate IIV should be used.

VACCINE STORAGE AND ADMINISTRATION

The AAP Storage and Handling Tip Sheet provides resources for practices to develop comprehensive vaccine management protocols to keep the temperature for vaccine storage constant during a power failure or other disaster (www2.aap.org/immunization/pediatricians/pdf/DisasterPlanning.pdf).

TABLE 2 LAIV4 Compared With IIV3 and IIV4

Vaccine Characteristic	LAIV4	IIV3	IIV4
Route of administration	Intranasal spray	Intramuscular or intradermal injection ^a	Intramuscular injection ^a
Type of vaccine	Live virus	Killed virus	Killed virus
Product	Attenuated, cold adapted	Inactivated subvirion or surface antigen	Inactivated subvirion or surface antigen
No. of included virus strains	4 (2 influenza A, 2 influenza B)	3 (2 influenza A, 1 influenza B)	4 (2 influenza A, 2 influenza B)
Vaccine virus strains updated	Annually	Annually	Annually
Frequency of administration ^b	Annually	Annually	Annually
Approved age groups	All healthy people aged 2–49 y	All people aged ≥6 mo (ID 18–64 y)	All people aged ≥6 mo
Interval between 2 doses in children	4 wk	4 wk	4 wk
Can be given to people with medical risk factors for influenza-related complications?	Not preferred	Yes	Yes
Can be given to children with asthma or children aged 2–4 y with wheezing in the previous year?	No ^c	Yes	Yes
Can be simultaneously administered with other vaccines?	Yes ^d	Yes ^d	Yes ^d
If <i>not</i> simultaneously administered, can be administered within 4 wk of another live vaccine?	No, recommended to space 4 wk apart	Yes	Yes
Can be administered within 4 wk of an inactivated vaccine?	Yes	Yes	Yes

Sources: American Academy of Pediatrics, Committee on Infectious Diseases. Recommendations for prevention and control of influenza in children, 2013–2014. *Pediatrics*. 2013;132(4):e1089–e1104; and Centers for Disease Control and Prevention. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2014–2015 influenza season. *MMWR Recomm Rep*. 2014;63(32):691–697.

^a The preferred site of IIV intramuscular injection for infants and young children is the anterolateral aspect of the thigh.

^b See Fig 2 for decision algorithm to determine number of doses of seasonal influenza vaccine recommended for children during the 2014–2015 influenza season.

^c LAIV4 is not recommended for children with a history of asthma. In the 2- through 4-y age group, there are children who have a history of wheezing with respiratory illnesses in whom reactive airway disease is diagnosed and in whom asthma may later be diagnosed. Therefore, because of the potential for increased wheezing after immunization, children 2 through 4 y of age with recurrent wheezing or a wheezing episode in the previous 12 mo should not receive LAIV4. When offering LAIV4 to children in this age group, a pediatrician should screen those who might be at higher risk of asthma by asking the parents or guardians of 2-, 3-, and 4-y-olds (24- through 59-mo-olds) the question, “In the previous 12 months, has a health care professional ever told you that your child had wheezing?” If the parents answer “yes” to this question, LAIV4 is not recommended for these children.

^d LAIV4 coadministration has been evaluated systematically only among children 12–15 mo of age with measles–mumps–rubella and varicella vaccines. IIV coadministration has been evaluated systematically only among adults with pneumococcal polysaccharide and zoster vaccines.

Any of the influenza vaccines can be administered at the same visit with all other recommended routine vaccines.

Intramuscular Vaccine

The IM formulation of IIV is shipped and stored at 2°C to 8°C (35°F–46°F). It is administered intramuscularly into the anterolateral thigh of infants and young children and into the deltoid muscle of older children and adults. The volume of vaccine is age dependent; infants and toddlers 6 months through 35 months of age should receive a dose of 0.25 mL, and all people 3 years (36 months) and older should receive 0.5 mL/dose.

Intradermal Vaccine

The ID formulation of IIV also is shipped and stored at 2°C to 8°C (35°F–46°F). It is administered intradermally only to people 18 through 64 years of age,

preferably over the deltoid muscle and only using the device included in the vaccine package. Vaccine is supplied in a single-dose, prefilled microinjection system (0.1 mL) for adults. The package insert should be reviewed for full administration details of this product.

Live Attenuated (Intranasal) Vaccine

The cold-adapted, temperature-sensitive LAIV4 formulation currently licensed in the United States must be shipped and stored at 2°C to 8°C (35°F–46°F) and administered intranasally in a prefilled, single-use sprayer containing 0.2 mL of vaccine. A removable dose divider clip is attached to the sprayer to administer 0.1 mL separately into each nostril. After administration of any live virus vaccine, at least 4 weeks should pass before another live virus vaccine is administered.

CURRENT RECOMMENDATIONS

Seasonal influenza immunization is recommended for all children 6 months and older. LAIV should be considered for *healthy* children 2 through 8 years of age who have no contraindications or precautions to the intranasal vaccine. This is based on a GRADE analysis done by the CDC, which concluded that there is greater relative efficacy of LAIV as compared with IIV against laboratory-confirmed influenza among younger children. If LAIV is not readily available, IIV should be used; vaccination should not be delayed to obtain LAIV. Particular focus should be on the administration of IIV for all children and adolescents with underlying medical conditions associated with an elevated risk of complications from influenza, including the following:

- Asthma or other chronic pulmonary diseases, including cystic fibrosis

Approach to Children With Presumed Egg Allergy

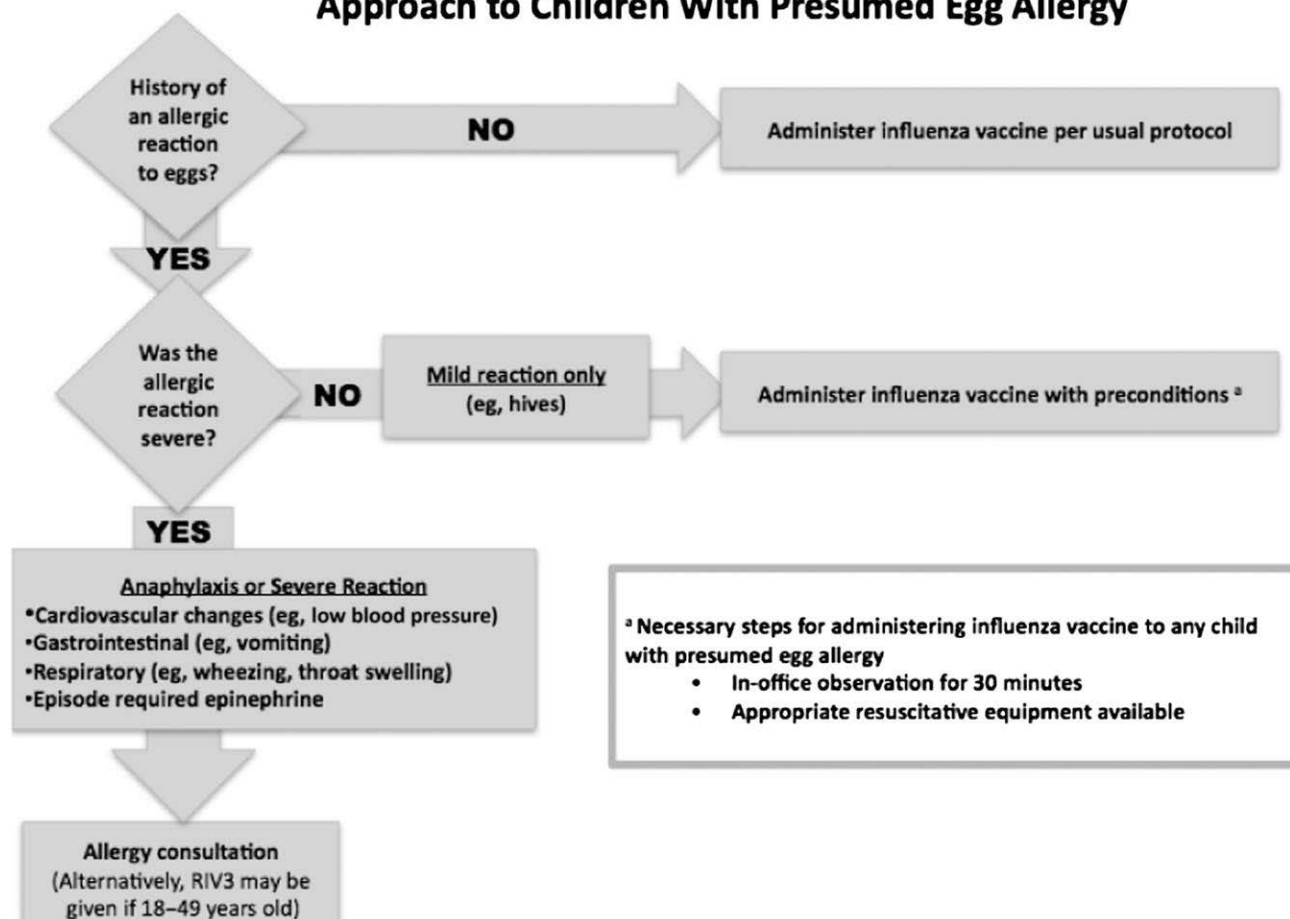


FIGURE 3

Precautions for administering IIV to presumed egg-allergic children.

- Hemodynamically significant cardiac disease
- Immunosuppressive disorders or therapy
- HIV infection
- Sickle cell anemia and other hemoglobinopathies
- Diseases that necessitate long-term aspirin therapy, including juvenile idiopathic arthritis or Kawasaki disease
- Chronic renal dysfunction
- Chronic metabolic disease, including diabetes mellitus
- Any condition that can compromise respiratory function or handling of secretions or can increase the risk of aspiration, such as neu-

rodevelopmental disorders, spinal cord injuries, seizure disorders, or neuromuscular abnormalities

Although universal immunization for all people 6 months and older is recommended for the 2014–2015 influenza season, particular immunization efforts with either IIV or LAIV should be made for the following groups to prevent transmission of influenza to those at risk, unless contraindicated:

- Household contacts and out-of-home care providers of children younger than 5 years and at-risk children of all ages (healthy contacts 2 through 49 years of age can receive either IIV or LAIV).
- Any woman who is pregnant or considering pregnancy (IIV only),

is in the postpartum period, or is breastfeeding during the influenza season. Studies have shown that infants born to immunized women have better influenza-related health outcomes. However, according to Internet panel surveys conducted by the CDC, only 51% of pregnant women reported receiving an influenza vaccine during the 2012–2013 season, even though both pregnant women and their infants are at higher risk of complications. In addition, data from some studies suggest that influenza vaccination in pregnancy may decrease the risk of preterm birth and of giving birth to infants who are small for gestational age. Pregnant women can receive the

influenza vaccine safely during any trimester.

- Children and adolescents of American Indian or Alaska Native heritage.
- HCP or health care volunteers. Despite the AAP recommendation for mandatory influenza immunization for all HCP,² many remain unvaccinated. As of November 2013, the CDC estimated that only 62.9% of HCP received the seasonal influenza vaccine. The AAP recommends mandatory vaccination of HCP, because HCP frequently come into contact with patients at high risk of influenza illness in their clinical settings.
- Close contacts of immunosuppressed people.

CONTRAINDICATIONS AND PRECAUTIONS

Minor illnesses, with or without fever, are not contraindications to the use of influenza vaccines, particularly among children with mild upper respiratory infection symptoms or allergic rhinitis.

Children Who Should Not Be Vaccinated With IIV

- Infants younger than 6 months.
- Children who have a moderate to severe febrile illness, on the basis of clinical judgment of the clinician.

Children Who Should Not Be Vaccinated With LAIV

- Children younger than 2 years.
- Children who have a moderate to severe febrile illness.
- Children with an amount of nasal congestion that would notably impede vaccine delivery.
- Children 2 through 4 years of age with a history of recurrent wheezing or a medically attended wheezing

episode in the previous 12 months because of the potential for increased wheezing after immunization. In this age range, many children have a history of wheezing with respiratory tract illnesses and are eventually diagnosed with asthma. Therefore, when offering LAIV to children 24 through 59 months of age, the pediatrician should screen them by asking the parent or guardian, “In the previous 12 months, has a health care professional ever told you that your child had wheezing?” If a parent answers “yes” to this question, LAIV is *not* recommended for the child. IIV would be recommended for the child to whom LAIV is not given.

- Children with the diagnosis of asthma.
- Children with a history of egg allergy.
- Children who have received other live virus vaccines within the last 4 weeks; however, other live virus vaccines can be given on the same day as LAIV.
- Children who have known or suspected immunodeficiency disease or who are receiving immunosuppressive or immunomodulatory therapies.
- Children who are receiving aspirin or other salicylates.
- Any woman who is pregnant or considering pregnancy.
- Children with any condition that can compromise respiratory function or handling of secretions or can increase the risk for aspiration, such as neurodevelopmental disorders, spinal cord injuries, seizure disorders, or neuromuscular abnormalities.
- Children taking an influenza antiviral medication should not receive LAIV until 48 hours after stopping the influenza antiviral therapy. If a child recently received LAIV but

has an influenza illness for which antiviral agents are appropriate, the antiviral agents should be given. Reimmunization may be indicated because of the potential effects of antiviral medications on LAIV replication and immunogenicity.

Children for Whom IIV Is Preferred

- Children with chronic underlying medical conditions, including metabolic disease, diabetes mellitus, other chronic disorders of the pulmonary or cardiovascular systems, renal dysfunction, or hemoglobinopathies. The safety of LAIV in these populations has not been established. These conditions are not contraindications but are listed under the “Warnings and Precautions” section of the LAIV package insert. A precaution is a condition in a recipient that might increase the risk or seriousness of an adverse reaction or complicate making another diagnosis because of a possible vaccine-related reaction. A precaution also may exist for conditions that might compromise the ability of the vaccine to produce immunity. Vaccination may be recommended in the presence of a precaution if the benefit of protection from the vaccine outweighs any risk.

IIV is the vaccine of choice for anyone in close contact with a subset of severely immunocompromised people (ie, those in a protected environment). IIV is preferred over LAIV for contacts of severely immunocompromised people because of the theoretical risk of infection attributable to LAIV strain in an immunocompromised contact of an LAIV-immunized person. Available data indicate a very low risk of transmission of the virus in both children and adults vaccinated with LAIV. HCP immunized with LAIV may continue to work in most units of a hospital, including the NICU and general oncology wards, using

standard infection control techniques. As a precautionary measure, people recently vaccinated with LAIV should restrict contact with severely immunocompromised patients for up to 7 days after immunization, although there have been no reports of LAIV transmission from a vaccinated person to an immunocompromised person. In the theoretical scenario in which symptomatic LAIV infection develops in an immunocompromised host, oseltamivir or zanamivir could be prescribed, because LAIV strains are susceptible to these antiviral medications.

SURVEILLANCE

Information about influenza surveillance is available through the CDC Voice Information System (influenza update, 888-232-3228) or at www.cdc.gov/flu/index.htm. Although current influenza season data on circulating strains do not necessarily predict which and in what proportion strains will circulate in the subsequent season, it is instructive to be aware of 2013–2014 influenza surveillance data and use them as a guide to empirical therapy until current seasonal data are available from the CDC. Information is posted weekly on the CDC Web site (www.cdc.gov/flu/weekly/fluactivity.htm).

VACCINE IMPLEMENTATION

These updated recommendations for prevention and control of influenza in children will have operational and fiscal effects on pediatric practice. Therefore, the AAP has developed implementation guidance on supply, payment, coding, and liability issues; these documents can be found at www.aapredbook.org/implementation. In addition, the AAP's Partnership for Policy Implementation has developed a series of definitions using accepted health information technology standards to assist in the implementation

of this guideline in computer systems and quality measurement efforts. This document is available at www2.aap.org/informatics/PPI.html.

USE OF ANTIVIRAL MEDICATIONS

Oral oseltamivir remains the antiviral drug of choice for the management of influenza infections. Inhaled zanamivir is an equally acceptable alternative but is more difficult to administer. Antiviral resistance can emerge quickly between seasons. If local or national influenza surveillance data indicate a predominance of a particular influenza strain with a known antiviral susceptibility profile, then empirical treatment can be directed toward that strain. For example, all the influenza A (H3N2) and influenza B viruses tested since October 1, 2013 were sensitive to oseltamivir and zanamivir during the 2013–2014 influenza season. Among the pH1N1 viruses tested for resistance, only 1.2% were found to be resistant to oseltamivir, and none were found to be resistant to zanamivir. In contrast, high levels of resistance to amantadine and rimantadine exist, so these drugs should not be used in the upcoming season unless resistance patterns change significantly.

- Current treatment guidelines for antiviral medications (Table 3) are applicable to both infants and children with suspected influenza when known virus strains are circulating in the community or when infants or children are confirmed to have seasonal influenza.
- Oseltamivir is available in capsule and oral suspension formulations. The commercially manufactured liquid formulation has a concentration of 6 mg/mL. If the commercially manufactured oral suspension is not available, the capsule may be opened and the contents mixed with simple syrup or Oral-Sweet

SF (sugar-free) by retail pharmacies to a final concentration of 6 mg/mL (Table 3).

- Continuous monitoring of the epidemiology, change in severity, and resistance patterns of influenza strains may lead to new guidance.

Treatment should be offered for:

- Any child hospitalized with presumed influenza or with severe, complicated, or progressive illness attributable to influenza, regardless of influenza immunization status or whether onset of illness occurred >48 hours before admission.
- Influenza infection of any severity in children at high risk of complications of influenza infection (Table 4), such as children younger than 2 years.

Treatment should be considered for:

- Any otherwise healthy child with influenza infection for whom a decrease in duration of clinical symptoms is felt to be warranted by his or her pediatrician. The greatest impact on outcome will occur if treatment can be initiated within 48 hours of illness onset but still should be considered if later in the course of illness.

Reviews of available studies by the CDC, the World Health Organization, and independent investigators have consistently found that timely oseltamivir treatment can reduce the risks of complications, including those resulting in hospitalization and death. Although a 2012 Cochrane review of studies primarily in outpatient settings suggested that oseltamivir may not be effective in preventing complications or hospitalizations from influenza, its authors correctly pointed out that the data reviewed were not always complete, were analyzed in a variety of treated populations, and used a number of clinical trial designs. In addition, a recently revised 2014 Cochrane

review of NAIs for influenza further evaluated published and previously unpublished data from randomized clinical trials largely in healthy outpatients with mild illness. Unlike other analyses of the efficacy of antiviral drugs, this Cochrane analysis included both influenza virus–infected and noninfected people with influenza-like illness. Given the specific antiviral activity of NAIs against influenza viruses, this analytic approach underestimates the treatment efficacy of NAIs and their valuable role in helping to lessen complications in those at high risk for them, including hospitalized patients. Furthermore, this review of outpatients was not designed

to assess the effect on severe outcomes such as hospitalizations or deaths.

Importantly, treatment with oseltamivir for children with presumed serious, complicated, or progressive disease, irrespective of influenza immunization status or even whether illness began greater than 48 hours before admission, continues to be recommended by the AAP, CDC, and Infectious Diseases Society of America (IDSA) (http://www.idsociety.org/Influenza_Statement.aspx). Earlier treatment provides better clinical responses. However, treatment after 48 hours of symptoms in adults and children with moderate to severe disease or with progressive disease has

been shown to provide some benefit and should be strongly considered. In previous years, the use of double-dose oseltamivir, particularly for those hospitalized with severe illness caused by pH1N1, was believed to provide better outcomes. However, recently published data from a randomized, prospective trial with 75% of subjects younger than 15 years documented no benefit of double-dose therapy over standard-dose therapy.

Dosages for antiviral agents for both treatment and chemoprophylaxis in children can be found in Table 3 and on the CDC Web site (<http://www.cdc.gov/flu/professionals/antivirals/index.htm>). Children younger than 2 years

TABLE 3 Recommended Dosage and Schedule of Influenza Antiviral Medications for Treatment and Chemoprophylaxis for the 2014–2015 Influenza Season: United States

Medication	Treatment (5 d)	Chemoprophylaxis (10 d)
Oseltamivir^a		
Adults	75 mg twice daily	75 mg once daily
Children ≥12 mo		
Body wt		
≤15 kg (≤33 lb)	30 mg twice daily	30 mg once daily
>15–23 kg (33–51 lb)	45 mg twice daily	45 mg once daily
>23–40 kg (51–88 lb)	60 mg twice daily	60 mg once daily
>40 kg (>88 lb)	75 mg twice daily	75 mg once daily
Infants 9–11 mo ^b	3.5 mg/kg per dose twice daily	3.5 mg/kg per dose once daily
Term infants 0–8 mo ^b	3 mg/kg per dose twice daily	3 mg/kg per dose once daily for infants 3–8 mo; not recommended for infants <3 mo, unless situation judged critical, because of limited safety and efficacy data in this age group
Preterm infants	See details in footnote ^c	
Zanamivir^d		
Adults	10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily
Children (≥7 y for treatment, ≥5 y for chemoprophylaxis)	10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily

Sources: Centers for Disease Control and Prevention. Antiviral agents for the treatment and chemoprophylaxis of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR-1):1–24; Kimberlin DW, Acosta EP, Prichard MN, et al. National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group. Oseltamivir pharmacokinetics, dosing, and resistance among children aged <2 y with influenza. *J Infect Dis*. 2013;207(5):709–720.

^a Oseltamivir is administered orally without regard to meals, although administration with meals may improve gastrointestinal tolerability. Oseltamivir is available as Tamiflu in 30-mg, 45-mg, and 75-mg capsules and as a powder for oral suspension that is reconstituted to provide a final concentration of 6 mg/mL. For the 6-mg/mL suspension, a 30-mg dose is given with 5 mL of oral suspension, a 45-mg dose is given with 7.5 mL oral suspension, a 60-mg dose is given with 10 mL oral suspension, and a 75-mg dose is given with 12.5 mL oral suspension. If the commercially manufactured oral suspension is not available, a suspension can be compounded by retail pharmacies (final concentration also 6 mg/mL), based on instructions that are present on the package label. In patients with renal insufficiency, the dose should be adjusted on the basis of creatinine clearance. For treatment of patients with creatinine clearance 10–30 mL/min, administer 75 mg, once daily, for 5 d. For chemoprophylaxis of patients with creatinine clearance 10–30 mL/min, administer 30 mg, once daily, for 10 d after exposure or 75 mg, once every other day, for 10 d after exposure (5 doses). See <http://www.cdc.gov/flu/professionals/antivirals/antiviral-drug-resistance.htm>.

^b Approved by the FDA for children as young as 2 wk of age. Given preliminary pharmacokinetic data and limited safety data, oseltamivir can be used to treat influenza in both term and preterm infants from birth because benefits of therapy are likely to outweigh possible risks of treatment.

^c Oseltamivir dosing for preterm infants. The weight-based dosing recommendation for preterm infants is lower than for term infants. Preterm infants may have lower clearance of oseltamivir because of immature renal function, and doses recommended for full-term infants may lead to very high drug concentrations in this age group. Limited data from the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group provide the basis for dosing preterm infants using their postmenstrual age (gestational age + chronological age): 1.0 mg/kg per dose, orally, twice daily, for those <38 wk postmenstrual age; 1.5 mg/kg per dose, orally, twice daily, for those 38 through 40 wk postmenstrual age; 3.0 mg/kg per dose, orally, twice daily, for those >40 wk postmenstrual age. For extremely premature infants (<28 wk postmenstrual age), consult a pediatric infectious disease physician.

^d Zanamivir is administered by inhalation using a proprietary “Diskhaler” device distributed together with the medication. Zanamivir is a dry powder, not an aerosol, and should not be administered with nebulizers, ventilators, or other devices typically used to administer medications in aerosolized solutions. Zanamivir is not recommended for people with chronic respiratory diseases, such as asthma or chronic obstructive pulmonary disease, which increase the risk of bronchospasm.

TABLE 4 People at Higher Risk of Influenza Complications Recommended for Antiviral Treatment of Suspected or Confirmed Influenza

Children <2 y
Adults ≥65 y
People with chronic pulmonary (including asthma), cardiovascular (except hypertension alone), renal, hepatic, hematologic (including sickle cell disease), or metabolic disorders (including diabetes mellitus) or neurologic and neurodevelopment conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy [seizure disorders], stroke, intellectual disability [mental retardation], moderate to severe developmental delay, muscular dystrophy, or spinal cord injury)
People with immunosuppression, including that caused by medications or by HIV infection
Women who are pregnant or postpartum (within 2 wk after delivery)
People <19 y who are receiving long-term aspirin therapy
American Indian or Alaska Native people
People who are morbidly obese (ie, BMI ≥40)
Residents of nursing homes and other chronic care facilities

Source: Centers for Disease Control and Prevention. Antiviral agents for the treatment and chemoprophylaxis of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR-1):1–24.

are at elevated risk of hospitalization and complications attributable to influenza. The FDA has licensed oseltamivir for children as young as 2 weeks of age. Given preliminary pharmacokinetic data and limited safety data, oseltamivir can be used to treat influenza in both term and preterm infants from birth because benefits of therapy are likely to outweigh possible risks of treatment.

Clinical judgment (on the basis of underlying conditions, disease severity, time since symptom onset, and local influenza activity) is an important factor in treatment decisions for pediatric patients who present with influenza-like illness. Antiviral treatment should be started as soon as possible after illness onset and should not be delayed while waiting for a definitive influenza test result because early therapy provides the best outcomes. Recently available rapid antigen tests have moderate sensitivity, even for the pH1N1 virus strain, but are not as sensitive as nucleic acid–based molecular diagnostic techniques (eg, polymerase chain reaction [PCR] assay). Decisions on treatment and infection control can be made based on positive rapid antigen tests. However, if rapid test results are negative, PCR techniques should be considered, because they have greater sensitivity for influenza infection than

antigen tests. Positive results are helpful, because they may reduce additional testing to identify the cause of the child's influenza-like illness. Treatment should not be withheld in high-risk patients awaiting PCR results.

People with suspected influenza who present with an uncomplicated febrile illness typically do not need treatment with antiviral medications unless they are at higher risk of influenza complications (eg, children with chronic medical conditions such as asthma, diabetes mellitus, hemodynamically significant cardiac disease, immunosuppression, or neurologic and neurodevelopmental disorders), especially in situations with limited antiviral medication availability. Antiviral treatment also should be considered for symptomatic siblings of children younger than 6 months or with underlying medical conditions that predispose them to complications of influenza. If there is a shortage of antiviral medications, local public health authorities should provide additional guidance about testing and treatment. In past years, local shortages have occurred based on uneven drug distribution, but national shortages have not occurred.

Randomized placebo-controlled studies showed that oseltamivir and zanamivir were efficacious when ad-

ministered as chemoprophylaxis to household contacts after a family member had laboratory-confirmed influenza. During the 2009 pandemic, the emergence of oseltamivir resistance was observed among people receiving postexposure prophylaxis. Decisions on whether to administer antiviral chemoprophylaxis should take into account the exposed person's risk of influenza complications, vaccination status, the type and duration of contact, recommendations from local or public health authorities, and clinical judgment. Optimally, postexposure chemoprophylaxis should only be used when antiviral agents can be started within 48 hours of exposure. Early treatment of high-risk patients without waiting for laboratory confirmation is an alternative strategy.

Although immunization is the preferred approach to infection prevention, chemoprophylaxis during an influenza outbreak, as defined by the CDC, is recommended

- For children at high risk of complications from influenza for whom influenza vaccine is contraindicated
- For children at high risk during the 2 weeks after influenza immunization
- For family members or HCP who are unimmunized and are likely to have ongoing, close exposure to
 - Unimmunized children at high risk
 - Unimmunized infants and toddlers who are younger than 24 months
- For control of influenza outbreaks for unimmunized staff and children in a closed institutional setting with children at high risk (eg, extended-care facilities)
- As a supplement to immunization among children at high risk, including children who are immunocompromised and may not respond to vaccine

- As postexposure prophylaxis for family members and close contacts of an infected person if those people are at high risk of complications from influenza
- For children at high risk and their family members and close contacts, as well as HCP, when circulating strains of influenza virus in the community are not matched with seasonal influenza vaccine strains, on the basis of current data from the CDC and local health departments

These recommendations apply to routine circumstances, but it should be noted that guidance may change on the basis of updated recommendations from the CDC in concert with antiviral availability, local resources, clinical judgment, recommendations from local or public health authorities, risk of influenza complications, type and duration of exposure contact, and change in epidemiology or severity of influenza. Chemoprophylaxis is not recommended for infants younger than 3 months, unless the situation is judged critical, because of limited safety and efficacy data in this age group.

Chemoprophylaxis Should Not Be Considered a Substitute for Immunization

Influenza vaccine should always be offered when not contraindicated, even after influenza virus has been circulating in the community. Antiviral medications currently licensed are important adjuncts to influenza immunization for control and prevention of influenza disease; toxicities associated with antiviral agents or indiscriminate use might limit availability. Pediatricians should inform recipients of antiviral chemoprophylaxis that risk of influenza is lowered but still remains while they are taking the medication, and susceptibility to influenza returns when medication is discontinued.

Oseltamivir use is not a contraindication to immunization with IIV (unlike LAIV). For recommendations about treatment and chemoprophylaxis against influenza, see Table 3. Among some high-risk people, both vaccination and antiviral chemoprophylaxis may be considered. Updates will be available at www.aapredbook.org/flu and www.cdc.gov/flu/professionals/antivirals/index.htm.

FUTURE NEEDS

For the 2014–2015 season, the AAP does not have a preferential recommendation for any type or brand of influenza vaccine over another. This is partly because the supply and distribution of newer vaccines may be limited during the 2014–2015 season. Moreover, post-marketing safety and vaccine effectiveness data are limited, precluding a full risk–benefit analysis of newer versus previously available products. However, such analyses will be performed as data become available, and in the future specific vaccines may be preferentially recommended for particular groups.

A large body of evidence indicates that even children with severe (anaphylactic) allergic reactions to the ingestion of eggs tolerate IIV in a single, age-appropriate dose. If, as expected, safety monitoring continues to show no elevated risk for anaphylactic reactions in egg-allergic recipients of IIV, special precautions regarding allergy consultation and waiting periods after administration to egg-allergic recipients beyond those recommended for any vaccine may no longer be recommended. Studies examining the safety of LAIV in egg-allergic recipients also are ongoing.

Efforts should be made to create adequate outreach and infrastructure to facilitate the optimal distribution of vaccine so that more people are immunized. Pediatricians also should become more involved in pandemic preparedness or disaster planning

efforts. A bidirectional partner dialogue between pediatricians and public health decision makers assists efforts to address children's issues during the initial state, regional, and local plan development stages. Additional information about disaster preparedness can be found at www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/children-and-disasters/Pages/Pediatric-Preparedness-Resource-Kit.aspx.

Health care for children is best provided in the medical home, which may have limited capacity to accommodate all patients (and their families) seeking influenza immunization. With the greater demand for immunization during each influenza season, the AAP and the CDC recommend vaccine administration at any visit to the medical home during influenza season when it is not contraindicated, at specially arranged vaccine-only sessions, and through cooperation with community sites, schools, and child care centers to provide influenza vaccine. If alternative venues, including pharmacies and other retail-based clinics, are used for immunization, a system of patient record transfer is beneficial in maintaining the accuracy of immunization records. Immunization information systems should be used whenever available. Two-dimensional barcodes have been used to facilitate more efficient and accurate documentation of vaccine administration, with limited experience to date. Multiple barriers appear to affect influenza vaccination coverage for children in foster care, refugee and immigrant children, and homeless children. Access to care issues, lack of immunization records, and questions about who can provide consent may be addressed by linking children with a medical home, using all health care encounters as vaccination opportunities, and more consistently using immunization registry data.

Cost-effectiveness and logistic feasibility of vaccinating everyone continue to be concerns. With universal immunization, particular attention is being paid to vaccine supply, distribution, implementation, and financing. Potential benefits of more widespread childhood immunization among recipients, their contacts, and the community include fewer influenza cases, fewer outpatient visits and hospitalizations for influenza infection, and a decrease in the use of antimicrobial agents, absenteeism from school, and lost parent work time. To administer antiviral therapy optimally in hospitalized patients with influenza who cannot tolerate oral or inhaled antiviral agents, FDA-approved intravenous NAIs for children also are needed.

Continued evaluation of the safety, immunogenicity, and effectiveness of influenza vaccine, especially for children younger than 2 years, is important. The potential role of previous influenza vaccination on overall vaccine effectiveness by virus strain and subject age in preventing outpatient medical visits, hospitalizations, and deaths continues to be evaluated. Continued assessment of the safety of LAIV is warranted as more children receive the vaccine annually. In addition, the routine use of LAIV in children with certain respiratory and nonrespiratory chronic medical conditions warrants additional consideration. There is also a need for more systematic health service research on influenza vaccine uptake and refusal as well as identification of methods to increase uptake. In addition, development of a safe, immunogenic vaccine for infants younger than 6 months is essential. Until such a vaccine is available for infants younger than 6 months, vaccination of their mothers during pregnancy is the best way to protect these infants. Breast-feeding also is recommended to protect against influenza viruses by activating

innate antiviral mechanisms, specifically type 1 interferons. Mandatory annual influenza immunization of all HCP has been implemented successfully at an increasing number of pediatric institutions. Future efforts should include broader implementation of mandatory immunization programs. Optimal prevention of influenza in the health care setting depends on the vaccination of at least 90% of HCP. Additional studies are needed to investigate the extent of offering to immunize parents and adult child care providers in the pediatric office setting; the level of family contact satisfaction with this practice; how practices handle the logistic, liability, legal, and financial barriers that limit or complicate this service; and, most importantly, how this practice will affect disease rates in children and adults. In addition, adjuvants have been shown to increase immune responses to influenza vaccines, but certain adjuvants have been associated with the development of narcolepsy in some studies. Additional studies on the effectiveness and safety of influenza vaccines containing adjuvants are needed. Finally, efforts to improve the vaccine development process to allow a shorter interval between identification of vaccine strains and vaccine production continue.

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Recommended Childhood and Adolescent Immunization Schedule—United States, 2015

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The 2015 recommended childhood and adolescent immunization schedule has been approved by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists. The 2015 format is similar to last year and includes a single schedule for people birth through 18 years of age. The yellow bars indicate the recommended age range for all children and contain a notation indicating the recommended dose number by age. The green bars indicate the recommended catch-up age. The purple bars designate the range for immunization for certain groups at high risk. The combined green and purple bar indicates the recommended age when hepatitis A vaccine catch-up is recommended. The white boxes show the ages when a vaccine is not recommended routinely. The catch-up schedule offers recommendations for children and adolescents 4 months through 18 years of age who start late or are >1 month behind.

Unlike previous years, the immunization schedules will not be published in *Pediatrics*. Readers are referred to the American Academy of Pediatrics Web site (http://redbook.solutions.aap.org/SS/Immunization_Schedules.aspx) or the Centers for Disease Control and Prevention Web site (<http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>) for the most recent edition of the immunization schedule, the full set of footnotes, and the catch-up schedule. This will ensure providers have the most current recommendations. The online schedule will be updated when new vaccines are licensed and recommendations for use are established and when a change is made to a recommendation for use of an existing vaccine. In addition, the Web site includes tables (job-aids) to assist in clarification of recommended use of *Haemophilus influenzae* type b, pneumococcal, and pertussis-containing vaccines as a function of age, the number of doses previously administered, and the time interval since the last dose.

Footnotes contain recommendations for routine vaccination, for catch-up vaccination, and for vaccination of children and adolescents with high-risk

conditions or in special circumstances. A parent-friendly vaccine schedule for children and adolescents is available at <http://www.cdc.gov/vaccines/schedules/index.html>.

An adult immunization schedule is published in February of each year and is available at www.cdc.gov/vaccines.

These schedules are revised annually to reflect current recommendations for the use of vaccines licensed by the US Food and Drug Administration and include the following specific changes from last year:

- A column has been added to the immunization schedule at 2 through 8 years to emphasize the availability of inactivated influenza vaccine and live-attenuated influenza vaccine starting at 2 years of age, as well as the need for 2 doses for some children in this age group. A second column has been added at 9 through 10 years to indicate when 2 doses are no longer needed. In addition, a purple bar has been added for young children 6 months to less than 12 months traveling outside the United States and who will need measles mumps rubella vaccine.
- Minor, clarifying word changes were made to the catch-up schedule with regard to *Haemophilus influenzae* type b; pneumococcal conjugate; tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis, adsorbed; hepatitis A; hepatitis B; polio; meningococcal; measles mumps rubella; and varicella vaccines.
- Minor, simplifying word changes were made to the footnotes relating

to diphtheria-tetanus-acellular pertussis and pneumococcal conjugate vaccines. The influenza vaccine footnote was updated to reflect revised contraindications and precautions for the live-attenuated influenza vaccine. The meningococcal footnote underwent extensive revision to clarify appropriate dosing schedules for high-risk infants and children for the 3 different vaccines.

Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System. Guidance about how to obtain and complete a Vaccine Adverse Event Reporting System form can be obtained at www.vaers.hhs.gov or by calling 800-822-7967. Additional information can be found in the *Red Book* and at *Red Book Online* (<http://redbook.solutions.aap.org/redbook.aspx>). Statements from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention that contain details of recommendations for individual vaccines, including recommendations for children with high-risk conditions, are available at www.cdc.gov/vaccines/pubs/ACIP-list.htm. Information on new vaccine releases, vaccine supplies, and interim recommendations resulting from vaccine shortages and statements on specific vaccines can be found at <http://redbook.solutions.aap.org/vaccine-status.aspx?gbosid=167073> and www.cdc.gov/vaccines/pubs/ACIP-list.htm.

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Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2015.**(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).**

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16–18 yrs
Hepatitis B ¹ (HepB)	1 st dose	←----- 2 nd dose -----→			←----- 3 rd dose -----→											
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose			←----- 4 th dose -----→				5 th dose				
Tetanus, diphtheria, & acellular pertussis ⁴ (Tdap: ≥7 yrs)														(Tdap)		
<i>Haemophilus influenzae</i> type b ⁵ (Hib)			1 st dose	2 nd dose	See footnote 5		←----- 3 rd or 4 th dose -----→ See footnote 5									
Pneumococcal conjugate ⁶ (PCV13)			1 st dose	2 nd dose	3 rd dose		←----- 4 th dose -----→									
Pneumococcal polysaccharide ⁶ (PPSV23)																
Inactivated poliovirus ⁷ (IPV: <18 yrs)			1 st dose	2 nd dose	←----- 3 rd dose -----→							4 th dose				
Influenza ⁸ (IIV; LAIV) 2 doses for some: See footnote 8					Annual vaccination (IIV only) 1 or 2 doses						Annual vaccination (LAIV or IIV) 1 or 2 doses		Annual vaccination (LAIV or IIV) 1 dose only			
Measles, mumps, rubella ⁹ (MMR)					See footnote 9		←----- 1 st dose -----→					2 nd dose				
Varicella ¹⁰ (VAR)							←----- 1 st dose -----→					2 nd dose				
Hepatitis A ¹¹ (HepA)							←----- 2-dose series, See footnote 11 -----→									
Human papillomavirus ¹² (HPV2: females only; HPV4: males and females)														(3-dose series)		
Meningococcal ¹³ (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥ 9 mos; MenACWY-CRM ≥ 2 mos)			See footnote 13											1 st dose		Booster

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

Range of recommended ages during which catch-up is encouraged and for certain high-risk groups

Not routinely recommended

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm>) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/acip>), the American Academy of Pediatrics (<http://www.aap.org>), the American Academy of Family Physicians (<http://www.aafp.org>), and the American College of Obstetricians and Gynecologists (<http://www.acog.org>).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States, 2015.

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Children age 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B ¹	Birth	4 weeks	8 weeks and at least 16 weeks after first dose. Minimum age for the final dose is 24 weeks.		
Rotavirus ²	6 weeks	4 weeks	4 weeks ²		
Diphtheria, tetanus, and acellular pertussis ³	6 weeks	4 weeks	4 weeks	6 months	6 months ³
<i>Haemophilus influenzae</i> type b ⁵	6 weeks	4 weeks if first dose was administered before the 1 st birthday. 8 weeks (as final dose) if first dose was administered at age 12 through 14 months. No further doses needed if first dose was administered at age 15 months or older.	4 weeks ⁵ if current age is younger than 12 months and first dose was administered at younger than age 7 months, and at least 1 previous dose was PRP-T (ActHib, Pentacel) or unknown. 8 weeks and age 12 through 59 months (as final dose) ⁵ • if current age is younger than 12 months and first dose was administered at age 7 through 11 months; OR • if current age is 12 through 59 months and first dose was administered before the 1 st birthday, and second dose administered at younger than 15 months; OR • if both doses were PRP-OMP (PedvaxHIB; Comvax) and were administered before the 1 st birthday. No further doses needed if previous dose was administered at age 15 months or older.	8 weeks (as final dose) This dose only necessary for children age 12 through 59 months who received 3 doses before the 1 st birthday.	
Pneumococcal ⁶	6 weeks	4 weeks if first dose administered before the 1 st birthday. 8 weeks (as final dose for healthy children) if first dose was administered at the 1 st birthday or after. No further doses needed for healthy children if first dose administered at age 24 months or older.	4 weeks if current age is younger than 12 months and previous dose given at <7months old. 8 weeks (as final dose for healthy children) if previous dose given between 7-11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was given before age 12 months. No further doses needed for healthy children if previous dose administered at age 24 months or older.	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus ⁷	6 weeks	4 weeks ⁷	4 weeks ⁷	6 months ⁷ (minimum age 4 years for final dose).	
Meningococcal ¹³	6 weeks	8 weeks ¹³	See footnote 13	See footnote 13	
Measles, mumps, rubella ⁹	12 months	4 weeks			
Varicella ¹⁰	12 months	3 months			
Hepatitis A ¹¹	12 months	6 months			
Children and adolescents age 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis ⁴	7 years ⁴	4 weeks	4 weeks if first dose of DTaP/DT was administered before the 1 st birthday. 6 months (as final dose) if first dose of DTaP/DT was administered at or after the 1 st birthday.	6 months if first dose of DTaP/DT was administered before the 1 st birthday.	
Human papillomavirus ¹²	9 years	Routine dosing intervals are recommended. ¹²			
Hepatitis A ¹¹	Not applicable (N/A)	6 months			
Hepatitis B ¹	N/A	4 weeks	8 weeks and at least 16 weeks after first dose.		
Inactivated poliovirus ⁷	N/A	4 weeks	4 weeks ⁷	6 months ⁷	
Meningococcal ¹³	N/A	8 weeks ¹³			
Measles, mumps, rubella ⁹	N/A	4 weeks			
Varicella ¹⁰	N/A	3 months if younger than age 13 years. 4 weeks if age 13 years or older.			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2015

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

For vaccine recommendations for persons 19 years of age and older, see the Adult Immunization Schedule.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.
- For purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Vaccine doses administered 4 days or less before the minimum interval are considered valid. Doses of any vaccine administered ≥ 5 days earlier than the minimum interval or minimum age should not be counted as valid doses and should be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see *MMWR, General Recommendations on Immunization and Reports* / Vol. 60 / No. 2; Table 1. *Recommended and minimum ages and intervals between vaccine doses* available online at <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>.
- Information on travel vaccine requirements and recommendations is available at <http://www.wnc.cdc.gov/travel/destinations/list>.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in *General Recommendations on Immunization* (ACIP), available at <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>; and American Academy of Pediatrics. "Immunization in Special Clinical Circumstances," in Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. *Red Book: 2012 report of the Committee on Infectious Diseases*. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

1. Hepatitis B (HepB) vaccine. (Minimum age: birth)

Routine vaccination:

At birth:

- Administer monovalent HepB vaccine to all newborns before hospital discharge.
- For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series at age 9 through 18 months (preferably at the next well-child visit).
- If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine regardless of birth weight. For infants weighing less than 2,000 grams, administer HBIG in addition to HepB vaccine within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if mother is HBsAg-positive, also administer HBIG for infants weighing 2,000 grams or more as soon as possible, but no later than age 7 days.

Doses following the birth dose:

- The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
- Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks), administer the third dose at least 8 weeks after the second dose AND at least 16 weeks after the **first** dose. The final (third or fourth) dose in the HepB vaccine series should be administered **no earlier than age 24 weeks**.
- Administration of a total of 4 doses of HepB vaccine is permitted when a combination vaccine containing HepB is administered after the birth dose.

Catch-up vaccination:

- Unvaccinated persons should complete a 3-dose series.
- A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
- For other catch-up guidance, see Figure 2.

2. Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV1 [Rotarix] and RV5 [RotaTeq])

Routine vaccination:

Administer a series of RV vaccine to all infants as follows:

- If Rotarix is used, administer a 2-dose series at 2 and 4 months of age.
- If RotaTeq is used, administer a 3-dose series at ages 2, 4, and 6 months.
- If any dose in the series was RotaTeq or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

Catch-up vaccination:

- The maximum age for the first dose in the series is 14 weeks, 6 days; vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
- The maximum age for the final dose in the series is 8 months, 0 days.
- For other catch-up guidance, see Figure 2.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks. Exception: DTaP-IPV [Kinrix]: 4 years)

Routine vaccination:

- Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15 through 18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose. However, the fourth dose of DTaP need not be repeated if it was administered at least 4 months after the third dose of DTaP.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine (cont'd)

Catch-up vaccination:

- The fifth dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
- For other catch-up guidance, see Figure 2.

4. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for both Boostrix and Adacel)

Routine vaccination:

- Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
- Tdap may be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
- Administer 1 dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks' gestation) regardless of time since prior Td or Tdap vaccination.

Catch-up vaccination:

- Persons aged 7 years and older who are not fully immunized with DTaP vaccine should receive Tdap vaccine as 1 dose (preferably the first) in the catch-up series; if additional doses are needed, use Td vaccine. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years should NOT be administered. Td should be administered instead 10 years after the Tdap dose.
- Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoid (Td) booster doses every 10 years thereafter.
- Inadvertent doses of DTaP vaccine:
 - If administered inadvertently to a child aged 7 through 10 years may count as part of the catch-up series. This dose may count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11 through 12 years.
 - If administered inadvertently to an adolescent aged 11 through 18 years, the dose should be counted as the adolescent Tdap booster.
- For other catch-up guidance, see Figure 2.

5. *Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks for PRP-T [ACTHIB, DTaP-IPV/Hib (Pentacel) and Hib-MenCY (MenHibrix)], PRP-OMP [PedvaxHIB or COMVAX], 12 months for PRP-T [Hiberix])

Routine vaccination:

- Administer a 2- or 3-dose Hib vaccine primary series and a booster dose (dose 3 or 4 depending on vaccine used in primary series) at age 12 through 15 months to complete a full Hib vaccine series.
- The primary series with ActHib, MenHibrix, or Pentacel consists of 3 doses and should be administered at 2, 4, and 6 months of age. The primary series with PedvaxHib or COMVAX consists of 2 doses and should be administered at 2 and 4 months of age; a dose at age 6 months is not indicated.
- One booster dose (dose 3 or 4 depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months. An exception is Hiberix vaccine. Hiberix should only be used for the booster (final) dose in children aged 12 months through 4 years who have received at least 1 prior dose of Hib-containing vaccine.
- For recommendations on the use of MenHibrix in patients at increased risk for meningococcal disease, please refer to the meningococcal vaccine footnotes and also to *MMWR* February 28, 2014 / 63(RR01);1-13, available at <http://www.cdc.gov/mmwr/PDF/rr/rr6301.pdf>.

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

5. *Haemophilus influenzae* type b (Hib) conjugate vaccine (cont'd)

Catch-up vaccination:

- If dose 1 was administered at ages 12 through 14 months, administer a second (final) dose at least 8 weeks after dose 1, regardless of Hib vaccine used in the primary series.
- If both doses were PRP-OMP (PedvaxHIB or COMVAX), and were administered before the first birthday, the third (and final) dose should be administered at age 12 through 59 months and at least 8 weeks after the second dose.
- If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a third (and final) dose at age 12 through 15 months or 8 weeks after second dose, whichever is later.
- If first dose is administered before the first birthday and second dose administered at younger than 15 months, a third (and final) dose should be given 8 weeks later.
- For unvaccinated children aged 15 months or older, administer only 1 dose.
- For other catch-up guidance, see Figure 2. For catch-up guidance related to MenHibrix, please see the meningococcal vaccine footnotes and also *MMWR* February 28, 2014 / 63(RR01);1-13, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6301.pdf>.

Vaccination of persons with high-risk conditions:

- Children aged 12 through 59 months who are at increased risk for Hib disease, including chemotherapy recipients and those with anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, immunoglobulin deficiency, or early component complement deficiency, who have received either no doses or only 1 dose of Hib vaccine before 12 months of age, should receive 2 additional doses of Hib vaccine 8 weeks apart; children who received 2 or more doses of Hib vaccine before 12 months of age should receive 1 additional dose.
- For patients younger than 5 years of age undergoing chemotherapy or radiation treatment who received a Hib vaccine dose(s) within 14 days of starting therapy or during therapy, repeat the dose(s) at least 3 months following therapy completion.
- Recipients of hematopoietic stem cell transplant (HSCT) should be revaccinated with a 3-dose regimen of Hib vaccine starting 6 to 12 months after successful transplant, regardless of vaccination history; doses should be administered at least 4 weeks apart.
- A single dose of any Hib-containing vaccine should be administered to unimmunized* children and adolescents 15 months of age and older undergoing an elective splenectomy; if possible, vaccine should be administered at least 14 days before procedure.
- Hib vaccine is not routinely recommended for patients 5 years or older. However, 1 dose of Hib vaccine should be administered to unimmunized* persons aged 5 years or older who have anatomic or functional asplenia (including sickle cell disease) and unvaccinated persons 5 through 18 years of age with human immunodeficiency virus (HIV) infection.

* Patients who have not received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months of age are considered unimmunized.

6. Pneumococcal vaccines. (Minimum age: 6 weeks for PCV13, 2 years for PPSV23)

Routine vaccination with PCV13:

- Administer a 4-dose series of PCV13 vaccine at ages 2, 4, and 6 months and at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination with PCV13:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up guidance, see Figure 2.

Vaccination of persons with high-risk conditions with PCV13 and PPSV23:

- All recommended PCV13 doses should be administered prior to PPSV23 vaccination if possible.
- For children 2 through 5 years of age with any of the following conditions: chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); diabetes mellitus; cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; solid organ transplantation; or congenital immunodeficiency:
 1. Administer 1 dose of PCV13 if any incomplete schedule of 3 doses of PCV (PCV7 and/or PCV13) were received previously.
 2. Administer 2 doses of PCV13 at least 8 weeks apart if unvaccinated or any incomplete schedule of fewer than 3 doses of PCV (PCV7 and/or PCV13) were received previously.
 3. Administer 1 supplemental dose of PCV13 if 4 doses of PCV7 or other age-appropriate complete PCV7 series was received previously.
 4. The minimum interval between doses of PCV (PCV7 or PCV13) is 8 weeks.
 5. For children with no history of PPSV23 vaccination, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.

6. Pneumococcal vaccines (cont'd)

- For children aged 6 through 18 years who have cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; generalized malignancy; solid organ transplantation; or multiple myeloma:
 1. If neither PCV13 nor PPSV23 has been received previously, administer 1 dose of PCV13 now and 1 dose of PPSV23 at least 8 weeks later.
 2. If PCV13 has been received previously but PPSV23 has not, administer 1 dose of PPSV23 at least 8 weeks after the most recent dose of PCV13.
 3. If PPSV23 has been received but PCV13 has not, administer 1 dose of PCV13 at least 8 weeks after the most recent dose of PPSV23.
- For children aged 6 through 18 years with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure), chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus, alcoholism, or chronic liver disease, who have not received PPSV23, administer 1 dose of PPSV23. If PCV13 has been received previously, then PPSV23 should be administered at least 8 weeks after any prior PCV13 dose.
- A single revaccination with PPSV23 should be administered 5 years after the first dose to children with sickle cell disease or other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; generalized malignancy; solid organ transplantation; or multiple myeloma.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a 4-dose series of IPV at ages 2, 4, 6 through 18 months, and 4 through 6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk of imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years and at least 6 months after the previous dose.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered.
- Regardless of the child's current age, IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up guidance, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV], 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) persons who have experienced severe allergic reactions to LAIV, any of its components, or to a previous dose of any other influenza vaccine; 2) children 2 through 17 years receiving aspirin or aspirin-containing products; 3) persons who are allergic to eggs; 4) pregnant women; 5) immunosuppressed persons; 6) children 2 through 4 years of age with asthma or who had wheezing in the past 12 months; or 7) persons who have taken influenza antiviral medications in the previous 48 hours. For all other contraindications and precautions to use of LAIV, see *MMWR* August 15, 2014 / 63(32);691-697 [40 pages] available at <http://www.cdc.gov/mmwr/pdf/wk/mm6332.pdf>.

For children aged 6 months through 8 years:

- For the 2014-15 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. Some children in this age group who have been vaccinated previously will also need 2 doses. For additional guidance, follow dosing guidelines in the 2014-15 ACIP influenza vaccine recommendations, *MMWR* August 15, 2014 / 63(32);691-697 [40 pages] available at <http://www.cdc.gov/mmwr/pdf/wk/mm6332.pdf>.
- For the 2015-16 season, follow dosing guidelines in the 2015 ACIP influenza vaccine recommendations.

For persons aged 9 years and older:

- Administer 1 dose.

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer a 2-dose series of MMR vaccine at ages 12 through 15 months and 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer a 2-dose series of VAR vaccine at ages 12 through 15 months and 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see *MMWR* 2007 / 56 [No. RR-4], available at <http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf>) have 2 doses of varicella vaccine. For children aged 7 through 12 years, the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A (HepA) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series at 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of HepA vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection. This includes persons traveling to or working in countries that have high or intermediate endemicity of infection; men having sex with men; users of injection and non-injection illicit drugs; persons who work with HAV-infected primates or with HAV in a research laboratory; persons with clotting-factor disorders; persons with chronic liver disease; and persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. The first dose should be administered as soon as the adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.

12. Human papillomavirus (HPV) vaccines. (Minimum age: 9 years for HPV2 [Cervarix] and HPV4 [Gardasil])

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11 through 12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series may be started at age 9 years.
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks); administer the third dose 24 weeks after the first dose and 16 weeks after the second dose (minimum interval of 12 weeks).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see Routine vaccination above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines. (Minimum age: 6 weeks for Hib-MenCY [MenHibrix], 9 months for MenACWY-D [Menactra], 2 months for MenACWY-CRM [Menveo])

Routine vaccination:

- Administer a single dose of Menactra or Menveo vaccine at age 11 through 12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of Menactra or Menveo with at least 8 weeks between doses.
- For children aged 2 months through 18 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer Menactra or Menveo vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up guidance, see Figure 2.

Vaccination of persons with high-risk conditions and other persons at increased risk of disease:

- Children with anatomic or functional asplenia (including sickle cell disease):
 1. Menveo
 - o *Children who initiate vaccination at 8 weeks through 6 months:* Administer doses at 2, 4, 6, and 12 months of age.
 - o *Unvaccinated children 7 through 23 months:* Administer 2 doses, with the second dose at least 12 weeks after the first dose AND after the first birthday.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
 2. MenHibrix
 - o *Children 6 weeks through 18 months:* Administer doses at 2, 4, 6, and 12 through 15 months of age.
 - o If the first dose of MenHibrix is given at or after 12 months of age, a total of 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.
 3. Menactra
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart. If Menactra is administered to a child with asplenia (including sickle cell disease), do not administer Menactra until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.
- Children with persistent complement component deficiency:
 1. Menveo
 - o *Children who initiate vaccination at 8 weeks through 6 months:* Administer doses at 2, 4, 6, and 12 months of age.
 - o *Unvaccinated children 7 through 23 months:* Administer 2 doses, with the second dose at least 12 weeks after the first dose AND after the first birthday.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
 2. MenHibrix
 - o *Children 6 weeks through 18 months:* Administer doses at 2, 4, 6, and 12 through 15 months of age.
 - o If the first dose of MenHibrix is given at or after 12 months of age, a total of 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.
 3. Menactra
 - o *Children 9 through 23 months:* Administer 2 primary doses at least 12 weeks apart.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
- For children who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or the Hajj, administer an age-appropriate formulation and series of Menactra or Menveo for protection against serogroups A and W meningococcal disease. Prior receipt of MenHibrix is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W.
- For children at risk during a community outbreak attributable to a vaccine serogroup, administer or complete an age- and formulation-appropriate series of MenHibrix, Menactra, or Menveo.
- For booster doses among persons with high-risk conditions, refer to *MMWR* 2013 / 62(RR02);1-22, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>.

For other catch-up recommendations for these persons, and complete information on use of meningococcal vaccines, including guidance related to vaccination of persons at increased risk of infection, see *MMWR* March 22, 2013 / 62(RR02);1-22, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>.

Reducing Injury Risk From Body Checking in Boys' Youth Ice Hockey

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- *Policy Statement*

POLICY STATEMENT

Reducing Injury Risk From Body Checking in Boys' Youth Ice Hockey

COUNCIL ON SPORTS MEDICINE AND FITNESS

KEY WORDS

athletic injury, injury prevention, concussion, body checking

ABBREVIATIONS

AAP—American Academy of Pediatrics

AE—athlete-exposure

CHIRPP—Canadian Hospitals Injury Reporting and Prevention Program

CI—confidence interval

IRR—injury rate ratio

OR—odds ratio

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abstract

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Ice hockey is an increasingly popular sport that allows intentional collision in the form of body checking for males but not for females. There is a two- to threefold increased risk of all injury, severe injury, and concussion related to body checking at all levels of boys' youth ice hockey. The American Academy of Pediatrics reinforces the importance of stringent enforcement of rules to protect player safety as well as educational interventions to decrease unsafe tactics. To promote ice hockey as a lifelong recreational pursuit for boys, the American Academy of Pediatrics recommends the expansion of nonchecking programs and the restriction of body checking to elite levels of boys' youth ice hockey, starting no earlier than 15 years of age. *Pediatrics* 2014;133:1151–1157

INTRODUCTION

Ice hockey is a high-speed sport enjoyed by increasing numbers of children and adolescents in an expanding geographic distribution of the United States. It can subsequently become a lifelong recreational activity, enjoyed by many adults well into their senior years. According to USA Hockey (the national governing body for amateur ice hockey in the United States), there were more than 350 000 youth (305 000 boys, 50 000 girls) younger than 19 years participating in hockey programs in 2011–2012, increased from approximately 200 000 in 2000, when the American Academy of Pediatrics (AAP) published “Safety in Youth Ice Hockey: The Effects of Body Checking.”^{1,2} Like football, rugby, and wrestling, boys' ice hockey is categorized as a collision sport in that intentional physical contact may be used as a strategic technique. A body “check” is defined as a defensive player's intentional tactic to separate the puck carrier from the puck—not to injure or intimidate the opposing player—with a distinct and definable moment of impact (“hit”). In contrast, body “contact” is also a defensive tactic in which the athlete's body is used to legally block or impede the progress of the puck carrier, without delivering a hit to separate the carrier from the puck. Unlike other collision sports, hockey is played on a hard surface, contained by unyielding walls (“boards”) and acrylic windows (“glass”). Previous safety interventions focused on protective equipment and enforcement of rules have largely eliminated dental, eye, and facial injuries in youth hockey and greatly decreased cervical spine injuries. However, because of ongoing concerns that a high

number and proportion of boys' ice hockey injuries are attributable to body checking, the AAP has elected to reassess its 2000 recommendation that "body checking should not be allowed in youth hockey for children age 15 years or younger." Because body checking is not allowed at any level of girls' or women's ice hockey, this statement focuses on boys' youth ice hockey.

INJURY EPIDEMIOLOGY

Every year in the United States, an estimated 12 590 players younger than 19 years seek care in the emergency department for ice hockey–related injuries³; the yearly estimated incidence of ice hockey–related injuries among 9- to 14-year-olds increased by 163% from 1990 to 2006.⁴ For the years 2008–2012, the total injury rate for boys' high school ice hockey in the United States ranged from 2.03 to 2.56 injuries per 1000 athlete-exposures (AEs, ie, 1 athlete participating in 1 practice or competition), with a game-related injury rate of 4.18 to 6.08 per 1000 AEs, second only to boys' high school football (total injury rate, 3.61–4.02 per 1000 AE; game-related injury rate, 11.28–12.72).^{5–8} For this same time period, the proportion of severe injuries (>21 days' time loss) sustained during competition in boys' ice hockey (6%–17%) was comparable to that in football (6%–12%). A companion AAP

policy statement on tackling in youth football is in development.

Risk of Injury From Body Checking

Youth ice hockey leagues are typically stratified by age (Table 1) and competition level, as determined by talent, which is often associated with increasing training time, volume, and intensity as well as more extensive travel to games and tournaments. Because there have been several rule changes in boys' youth ice hockey over the past decade, the association between body checking and injury has become a focus of rigorous scientific examination (Table 2). Several investigators have examined cross-sectional data from the Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) injury surveillance system. A 2006 analysis of data on 4736 hockey injuries from CHIRPP between 1995 and 2002 found that the majority of the injuries in younger divisions (10–13 years of age) occurred in Ontario, where body checking was allowed at those ages, and nearly half of those injuries were related to checking.⁹ Another analysis of CHIRPP data from 1994 through 2004 on 8552 hockey-related injuries (52.2% attributable to body checking), after a rule change in 1998 that lowered the age for body checking (from 12–13 years to 10–11 years of age), showed that the odds of a body-checking-related injury increased twofold in

the newly allowed checking divisions.¹⁰ In contrast, a retrospective analysis of data from 1997 through 2007 found that the number of body-checking-related injuries for which players were treated in 2 Ontario emergency departments did not change significantly after a rule change in 2002 that lowered the age at which body checking was introduced from 12 to 13 years to 9 to 10 years of age.¹¹ Research examining the same 2002 rule change in a data set from Alberta similarly noted no increase in visits to emergency departments for body-checking-related injuries in that province.¹² However, the majority of other cohorts studied have demonstrated increased risk of injury with body checking.

In a 5-year study of youth ice hockey players 4 to 18 years of age, injuries from unintentional collisions were more common than were injuries from intentional contact,¹³ but the injury rates for both intentional and unintentional collisions were over 3 times higher (and the overall risk of injury nearly 4 times higher) in divisions that allowed body checking.¹⁴ A 2006 Canadian study of 986 youth ice hockey players 9 to 16 years of age estimated that 45% of all injuries occurred as a result of body checking.¹⁵ Comparisons within the same youth ice hockey programs have demonstrated that older age groups that allowed body checking sustained 3 to 5 times higher injury rates than the youngest age group, which did not allow checking.¹⁵ A large prospective study comparing 2 cohorts of 11- and 12-year-olds (Pee Wee) in Canadian provinces with (Alberta) and without (Quebec) body checking demonstrated that the rate of injury was more than 3 times higher in Alberta, including severe injury defined as time loss more than 1 week (injury rate ratio [IRR], 3.30; 95% confidence interval

TABLE 1 Current Age Jurisdictions in Youth Ice Hockey in North America^a

Category	Age (y) on December 31 of the Playing Season	Where Body Checking Is Allowed in 2013–2014 Season
Initiation (in Canada)	<7	Nowhere
Mite (US), Novice (Canada)	7 and 8	Nowhere
Squirt (US), Atom (Canada)	9 and 10	Nowhere
Pee Wee	11 and 12	Nowhere ^{b,c}
Bantam	13 and 14	US, Canada
Midget	15–17	US, Canada

^a Age categories were shifted down by 1 y in Canada in 2002.

^b In the United States, age of legal body checking in games raised from Pee Wee to Bantam starting with 2011–2012 season.

^c In Canada, age of legal body checking in games raised from Pee Wee to Bantam starting with 2013–2014 season.

TABLE 2 Estimated Risk of All Injury and Concussion From Body Checking

Study	Estimate of Risk of Body Checking (All Injury)	Estimate of Risk of Body Checking (Concussion)
Hagel, 2006 ⁴⁷	Rate ratio 1.9 (CI 1.4–2.4)	Rate ratio 3.4 (CI 1.4–8.4)
Emery, 2006 ¹⁵	Pee Wee, RR 2.97 (CI 1.63–5.8) Bantam RR 3.72 (CI 2.08–7.14) Midget RR 5.43 (CI 3.14–10.17)	Pee Wee RR 3.4 (0.93–18.61) Bantam RR 4.04 (1.17–21.54) Midget RR 3.41 (1.02–17.87)
Macpherson, 2006 ⁹	OR 1.83 (CI 1.58–2.11)	OR 1.42 (0.98–2.05)
Emery, 2010 ¹⁶	IRR 3.26 (CI 2.31–4.60)	IRR 3.88 (1.91–7.89)
Cusimano, 2011 ¹⁰	OR 2.20 (CI 1.70–2.84)	OR 10.08 (2.35–43.29)
Darling, 2011 ¹³	Rate ratio 3.75 (CI 1.51–9.34)	

RR, relative risk.

[CI], 1.77–6.17).¹⁶ Two systematic reviews of the literature published in 2009 (20 studies) and 2010 (10 studies) have examined the association between body checking and injury in boys' ice hockey. All but 1 of their included studies demonstrated that body checking increases the risk of all injuries, with the meta-analysis of 5 studies performed by Emery et al reporting a combined IRR of 2.45 (95% CI, 1.7–3.6).^{17,18}

Specific Risk of Concussion

As noted in the 2010 AAP clinical report "Sport-Related Concussion in Children and Adolescents," concussion is an increasingly recognized concern in many youth sports in the United States, including ice hockey.¹⁹ A recent study of high school sports revealed that the concussion rate in boys' ice hockey (5.4 per 10 000 AEs) was second only to football (6.4 per 10 000 AEs); however, concussions accounted for a greater proportion of total injuries in boys' ice hockey (22.2%) than any of the other 20 sports, with 30% of the concussions in ice hockey resulting from a player being body checked.²⁰ Other estimates of the proportion of concussions resulting from being checked and/or delivering the check are as high as 30% to 70%.^{5–8} Concussion was reported as the most common specific injury type in Canadian minor boys' ice hockey, with a higher risk of concussion in age

groups that allowed legal body checking.¹⁵ Studies demonstrating an increased risk of injury related to body checking also demonstrated increased risk of concussion (Table 2). The meta-analysis by Emery et al of 4 studies estimated a combined odds ratio (OR) of 1.71 (95% CI 1.2–2.44) for body checking as a risk factor for concussion,¹⁷ whereas the prospective cohort study by Emery et al comparing Canadian provinces that allowed body checking in Pee Wee (11 and 12 years of age) boys' hockey found an IRR of 3.61 (95% CI 1.16–11.23) for severe concussion (more than 10 days lost from sport).¹⁶

Recent research has suggested that body collisions may have adverse effects without causing frank concussion. Studies using in-helmet accelerometers showed that exposure to repetitive head impact sustained by collegiate football and ice hockey players was associated with significant declines on neuropsychological cognitive testing compared with non-collision collegiate sports athletes over 1 playing season, independent of concussion diagnosis.²¹ Using similar technology, female intercollegiate ice hockey players, who are not allowed to check, sustained less frequent and lower magnitude head impacts than their male counterparts.²² This nascent area of investigation raises the concern that even early recognition and proper management of concussion—

a form of tertiary injury prevention—may be inadequate protection for the central nervous system.

Risks of "Aggressive Playing Style"

Body checking is associated with a more aggressive style of play, and aggressive play is associated with more severe injury. Players in leagues in which body checking is allowed have been shown to have lower levels of empathy, to have higher levels of aggression, and to respond more positively to statements about injuring another player with a body check to increase their team's chances of winning as well as body checking an opposing player even if they knew it would injure the other player.²³ A study examining rule infractions from 55 games at the Bantam level in 2 Canadian provinces revealed that illegal collisions or infractions, categorized as boarding, charging, checking from behind, elbowing, and intentional head contact, resulted in higher linear head accelerations and more severe head impacts than legal collisions.²⁴ More frequent and higher-intensity physical contact occurs in leagues that allow body checking.²⁵ An aggressive style of play (such as lunging or launching at the opponent) to ensure physical contact with disregard for the location of the puck has been observed in players at the Bantam level.²⁶ These data suggest that delaying body checking until later ages may also reduce aggressive play overall, which could lead to an even greater reduction in injury rates.

RISK OF AGE, SIZE, OR MATURITY DISCREPANCY

The 2000 AAP statement expressed concern that large discrepancies in relative age, size, and maturity may lead to an increased injury rate in those who are younger, smaller, and less physically developed. Most studies

that have examined age as a risk factor have found that older relative age, not younger, is associated with a higher rate of injury, particularly at higher levels of competition.^{27,28} It has been suggested that in these analyses, age was a proxy for magnitude or intensity of exposure. In 2 studies that examined differences in injury proportions in players in their first and second constituent years within age categories, injured players were more likely to be in constituent year 2 in the Atom (7 and 8 years of age) and Pee Wee (11 and 12 years of age) divisions and in the highest level of competition.^{16,29} In contrast, Bantam (13 and 14 years of age) players in their first year have been determined to have an increased risk of injury.²⁷ This is likely because the Bantam level contains the broadest range of physical maturity and body size.

Although the few studies that have examined the association between injury risk and physical maturity, as determined by Tanner staging, bone age, or other noninvasive measures, also have suggested that more advanced players sustain more injuries, there is no research examining the risk of injury attributable to athletes of discrepant maturity status directly competing and potentially colliding.^{30,31} Nonetheless, the range of physical development represented in the 13- and 14-year-old Bantam age category, which spans the typical male peak height velocity at 13.5 years of age, is wide enough to cause concern, with the height and weight of male Bantam players reported to differ by as much as 41 cm and 48 kg, respectively.³² An anthropomorphic study of youth football players in Michigan demonstrated a mean weight of 38.6 kg and BMI of 17.5 kg/m² in 13-year-olds categorized as “late maturing,” and “early maturing” 14-year-olds had corresponding means of 77.3 kg weight and 26.6 kg/m²

BMI.³³ Pop Warner Youth Football addresses this issue by restricting players above certain size thresholds to specified positions on the field (offensive and defensive line) where high-speed collisions are less likely. In a single study, smaller Pee Wee (11 and 12 years of age, ≤ 37 kg) but not Bantam (13 and 14 years of age, ≤ 52 kg) youth hockey players have been determined to be at increased risk of injury, but the authors’ chosen 25th percentile weight cut points may not have had adequate sensitivity.^{16,27}

SAFETY STRATEGIES IN YOUTH ICE HOCKEY

Protective Equipment

Ice hockey players wear head-to-toe protective equipment. Although studies proving the merit of most of the gear is lacking, the speed of the puck and the use of curved sticks support its continued use. The piece of equipment that has generated the greatest controversy has been the helmet and facemask. Although some manufacturers have claimed protection from concussion for their particular models, no helmets have demonstrated evidence of such effect. Nonetheless, it is worth reinforcing that investigators have consistently found the overall injury rate to be significantly lower in players with helmets and full-face shield protection.^{34–40}

Rule Changes and Enforcement

The Canadian Ice Hockey Spinal Registry identified mechanisms of catastrophic cervical spine injury in the 1980s.⁴¹ Decreases in the incidence of these injuries followed more stringent enforcement of rules to prevent checking from behind, particularly near or into the boards, in addition to educational interventions. For the

2012–2013 season, the National Federation of State High School Associations approved rule changes to further strengthen enforcement aimed at eliminating dangerous play in hockey games. Hitting an opponent from behind into the boards or the goal frame is now considered a flagrant violation resulting in a game disqualification. The 2010 Ice Hockey Summit on Concussion called for a zero-tolerance policy with regard to any contact to the head, whether intentional or incidental.⁴² Nevertheless, Emery and Meeuwisse reported in 2006 that 97% of body-checking-related injuries were sustained by a player receiving a check, but only 15% of these injuries resulted in a penalty.¹⁵

Coaching and Education

Programs in both the United States and Canada that have emphasized coach and player education to teach youth to keep their heads up, especially when they are about to receive a check, and to respect their opponents by not checking them from behind have also coincided with a decrease in the incidence of cervical spine injury. ThinkFirst Canada’s SMART HOCKEY initiative and USA Hockey’s Heads Up Hockey curriculum aim to apply similar techniques to concussion recognition and prevention, but the effectiveness of these programs has yet to be assessed. USA Hockey’s American Development Model emphasizes skill and skating development free from fear of being body checked at younger ages, while implementing a progressive curriculum to teach proper body control, angling, and body contact, reserving body-checking skills until the 11- to 12-year-old age group.

Minnesota’s Hockey Education Program was implemented in 2004 to provide safer and more enjoyable

participation through Fair Play, a program first introduced 2 decades ago, that rewards teams with good sportsmanship specifically by allowing them to earn additional points for receiving fewer penalties.⁴³ In a 1999 study, the injury rate was 5 times higher in games played without the Fair Play rules in a tournament of Minnesota high school–age community-based teams.⁴⁴ Unfortunately, a 2005 study evaluating the effectiveness of the fair play concept in Quebec reported no significant difference in the injury rate, with either delivering or receiving a body check the primary cause for almost half of the injuries.⁴⁵ Several other interventions to promote safer play in youth ice hockey implemented both before and since the 2000 AAP statement similarly lack evidence for effectiveness in reducing injury rates.⁴⁶

No Protective Effect of Earlier Introduction of Body Checking

Proponents of body checking suggest that earlier introduction of body checking will increase skill and decrease injury related to body checking in older age groups, but there is limited evidence to support this potential effect. Older players (14–15 years of age) from a Canadian province that allowed checking at a younger age demonstrated an increased odds of a checking-related injury (OR, 1.90; 95% CI, 1.36–2.66) compared with their peers in a province allowing checking for the first time.⁹ After a lowering of age classifications by Hockey Canada in 2002, injury rates among 10-year-old Squirts (body checking never allowed) and 12-year-old Pee Wees (body checking always allowed) in Alberta did not change, but 11-year-old Pee Wee players newly allowed to body check sustained a significantly higher number of injuries.⁴⁷ A

subsequent prospective cohort study of almost 2000 male players 13 to 14 years of age, comparing injury rates in those with 2 years of body-checking experience with those being introduced to body checking for the first time, demonstrated that the game-related overall rates of injury, concussion, and concussion with more than 10 days of time loss were not significantly lower in players with 2 years of body-checking experience.²⁷ The injury rate associated with body checking was higher than other mechanisms of injury, and the rate of injury from body checking was not significantly lower in the group with body-checking experience (IRR, 0.82; 95% CI, 0.59–1.15), although the risk of injury resulting in greater than 1 week of time loss from sport was 33% lower among players with 2 years of body-checking experience.

OFFICIAL POLICY OF MEDICAL ASSOCIATIONS REGARDING HOCKEY SAFETY

Since the 2000 AAP statement, the American Osteopathic Academy of Sports Medicine (2002), the Canadian Academy of Sports Medicine (2007), and the Canadian Pediatric Society (2012) have released position statements about injuries in youth ice hockey. USA Hockey raised the age of legal body checking in games from Pee Wee (11 and 12 years of age) to Bantam (13 and 14 years of age) for the 2011–2012 season subsequent to the 2010 Ice Hockey Summit, which called for postponing legal body checking in youth games until 13 years of age. State and local youth hockey associations can offer leagues without body checking—often called “recreational”—at all ages, but competition with high school and other elite hockey programs that may promise the potential for advancement to higher levels of ice

hockey, which typically sanction body checking, may make this option rare in many communities.

CONCLUSIONS

There is consistent evidence that body checking remains a significant risk factor for injury at all levels of boys' youth ice hockey. Concussion is a particularly concerning problem and is often the result of body-checking activity. Body checking can also be associated with more aggressive play that further increases the risk of serious injury. The delay of body checking to higher ages has been shown to decrease risk of injury in 11- and 12-year-olds. Although data for older boys is less extensive, it is reasonable to conclude that removing body checking would reduce injury rates and severity at all ages, particularly benefitting 13- and 14-year-olds, who may be more vulnerable because of wide discrepancies in physical maturity.

RECOMMENDATIONS

In the continued interest of promoting boys' youth ice hockey as a safe, life-long recreational pursuit, the AAP recommends:

1. Expansion of nonchecking programs for boys aged 15 years and older. Pediatricians should advocate for development of these programs in their communities and encourage their patients to participate in them.
2. Restriction of body checking in boys' ice hockey games to the highest competition levels (eg, AAA, AA, Tier I, Tier II), starting no earlier than 15 years of age. Body-checking skills could be taught in practices starting at 13 years of age for those players geared to elite participation.

3. Strict enforcement of zero-tolerance rules against any contact to the head, whether incidental or intentional.
4. Reinforcement of rules to prevent body contact from behind, particularly into or near the boards.
5. Continued emphasis on coaching and education to prevent body contact from behind.
6. More research into the effects of legal body checking, including specific attention to injury risk attributable to differences in size and physical maturity.

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Referral to Pediatric Surgical Specialists

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- *Policy Statement*

POLICY STATEMENT

Referral to Pediatric Surgical Specialists

abstract

FREE

The American Academy of Pediatrics, with the collaboration of the Surgical Sections of the American Academy of Pediatrics, has created referral recommendations intended to serve as voluntary practice parameters to assist general pediatricians in determining when and to whom to refer their patients for pediatric surgical specialty care. It is recognized that these recommendations may be difficult to implement, because communities vary in terms of access to major pediatric medical centers. Limited access does not negate the value of the recommendations, however, because the child who needs specialized surgical and anesthetic care is best served by the skills of the appropriate pediatric surgical team. Major congenital anomalies, malignancies, major trauma, and chronic illnesses (including those associated with preterm birth) in infants and children should be managed by pediatric medical subspecialists and pediatric surgical specialists at pediatric referral centers that can provide expertise in many areas, including the pediatric medical subspecialties and surgical specialties of pediatric radiology, pediatric anesthesiology, pediatric pathology, and pediatric intensive care. The optimal management of the child with complex problems, chronic illness, or disabilities requires coordination, communication, and cooperation of the pediatric surgical specialist with the child's primary care pediatrician or physician. *Pediatrics* 2014;133:350–356

When a surgical condition has been identified in a child, ideally a pediatric surgical specialist should be called to address the issues related to this condition with the family and the respective pediatrician. It is recognized that communities differ in their medical resources. Specialists of all varieties tend to concentrate in areas of higher population density. In communities where it would be a hardship to the family and the child to travel long distances, the family, in conjunction with the primary care pediatrician/physician, should weigh the advantages of traveling to a center with a pediatric surgical specialist for surgical care. The primary care pediatrician or physician should consider calling the pediatric surgical specialist to discuss whether a consultation is advised in cases in which, geographically, the specialist is not near.

Finally, however, it should be noted that these recommendations are voluntary for practice management. Each pediatrician must make an independent judgment in each case on the basis of facts and circumstances presented to him or her. Whereas in some areas evidence

SURGICAL ADVISORY PANEL

KEY WORDS

referral, surgical specialists, pediatric surgery, oral surgery, anesthesiology, pathology, radiology, intensive care

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is available for better outcomes with specialist assessment and treatment, these recommendations are, in large part, derived from expert opinion of children's surgical specialists.

REFERRAL TO A CONGENITAL HEART SURGEON

Care of neonates, infants, children, and teenagers with congenital heart disease should occur at specialized centers that include the following: congenital heart surgeons, pediatric cardiologists subspecializing in invasive and noninvasive cardiology, pediatric cardiac anesthesiologists, and pediatric cardiac critical care specialists. Congenital heart surgeons operate on the heart and great vessels of neonates, infants, children, teenagers, and adults with congenital heart disease. A congenital heart surgeon has completed training in general surgery and thoracic surgery, is certified by the American Board of Thoracic Surgery, and has further specialized in the surgical treatment of congenital heart disease. The American Board of Thoracic Surgery now offers a subspecialty certificate in congenital heart surgery that can be earned by those Diplomates of the American Board of Thoracic Surgery who have specialized in congenital heart surgery, including surgeons presently in the practice of congenital heart surgery and those completing approved training programs. This certificate recognizes training and experience in the care of individuals with congenital heart disease of all ages. Congenital heart surgeons should care for the following groups of patients:

- all neonates, infants, children, and teenagers with congenital heart disease requiring heart surgery;
- adults with complex congenital heart disease requiring heart surgery;

- all neonates, infants, children, and teenagers with acquired heart disease requiring cardiac surgery (eg, endocarditis, cardiac tumors, Kawasaki disease); and
- all neonates, infants, children, and teenagers with end-stage heart disease requiring transplantation or mechanical support, whether attributable to congenital heart disease or myopathies.

REFERRAL TO A PEDIATRIC DENTIST

A pediatric dentist has completed 4 years of dental school and a 2- to 3-year postgraduate residency in pediatric dentistry. The American Board of Pediatric Dentistry offers a subspecialty certificate in pediatric dentistry that can be earned by those Diplomates of the American Board of Dentistry who have specialized in pediatric dentistry by completing approved training programs. This certificate recognizes training and experience in the provision of oral health care in children. Postgraduate training for a pediatric dentist includes training in infant and early child oral disease risk assessment; anticipatory guidance; hospital dentistry; oral sedation; general anesthesia; infant oral health care; behavior guidance; specialized care for the primary, mixed, and adult dentitions; pediatric oral pathology; prevention; and interventional orthodontics. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years). All children should have a Dental Home within 6 months of the eruption of the first tooth.

A pediatric patient who presents with any of the following conditions should be referred for prompt consultation to a pediatric dentist or a general dentist who maintains

a high level of competence in the care of children:

- an infant determined to have high caries risk through a caries risk assessment;
- an infant/child/adolescent with a severe developmental disability that makes management of behavior and clinical care challenging;
- an infant/child/adolescent with rampant or extensive dental caries requiring oral sedation or general anesthesia for treatment;
- an infant/child/adolescent preparing to undergo radiation therapy, chemotherapy, and/or hematopoietic stem cell transplantation;
- an infant/child/adolescent who is medically compromised and whose medical condition would deteriorate without appropriate dental treatment;
- an infant/child/adolescent with a facial swelling of unknown origin;
- a child with oral habits (ie, thumb sucking, pacifier, tongue thrust) that may require intervention to prevent or improve a dental malocclusion;
- an infant/child/adolescent with a possible oral abnormality;
- a child/adolescent for the management of prematurely loose teeth and/or periodontal disease;
- an infant/child/adolescent with a cleft lip/palate or other craniofacial anomaly;
- a child/adolescent who is intending to participate in contact athletic activities that require fabrication of an athletic mouth guard;
- an infant/child/adolescent with suspected dental neglect or abuse;
- an infant/child/adolescent who suffers dental trauma (ie, tooth fracture, intrusion, luxation, and avulsion); or

- an infant, child and/or adolescent whose caregiver requests the care of a pediatric dental specialist.

Referral of a patient to a pediatric dentist may result in referrals to other dental specialists (orthodontist, oral surgeon, endodontist, periodontist, etc) for appropriate care, with the pediatric dentist managing the care and referral of the patient.

REFERRAL TO A PEDIATRIC NEUROLOGIC SURGEON

A pediatric neurosurgeon is identified by board certification. The American Board of Pediatric Neurologic Surgery offers a subspecialty certificate in pediatric neurologic surgery that can be earned by those Diplomates of the American Board of Neurologic Surgery who have specialized in pediatric neurologic surgery by completing approved training programs. This certificate recognizes training and experience in the care of children with neurologic surgical problems, as well as the care of congenital disorders throughout the life span, as demonstrated by a minimum of a 75% pediatric neurosurgical operative caseload. It is recognized that in an era of increasing neurosurgical subspecialization, children with particular disorders (eg, intracranial aneurysms) may be better served by a specialist experienced with that specific disorder. The pediatric neurosurgeon is usually in the best position to determine the most appropriate balance of care for both the child and condition by virtue of access to other regional pediatric and neurosurgical specialists. With these comments in mind, the following recommendations are suggested for referral of the infant (0–1 year), child (2–12 years), and adolescent (13–18 years) to a pediatric neurosurgical specialist.

- All infants and children requiring neurosurgical operative care should be cared for by a pediatric neurosurgeon if one is within reasonable proximity. However, it is recognized that under some circumstances, the distance to the nearest pediatric neurosurgeon is prohibitive, and it may be necessary for a general neurosurgeon to provide care; the benefits of each option should be considered on an individual basis.
- Infants and children with traumatic head, spine, spinal cord, and peripheral nerve injuries may be stabilized at a local hospital but should then be transferred to a center having both pediatric neurosurgical expertise and a system in place to care for the traumatically injured child. Infants and children with suspected abusive head trauma should also be evaluated by a pediatric neurosurgeon as part of a team of dedicated pediatric child abuse specialists.
- Infants, children, and adolescents with benign and malignant central nervous system tumors (including tumors involving the brain, spinal cord, meninges, spine, pituitary gland, and peripheral nerves) should be referred from the outset to a pediatric neurosurgeon and other dedicated pediatric cancer specialists.
- All infants, children, and adolescents with congenital brain and spinal cord malformations (including spina bifida) should be cared for by a pediatric neurosurgeon as part of a multidisciplinary medical-surgical team (such as a spina bifida clinic).
- All infants, children, and adolescents with disorders of the craniofacial skeleton (eg, craniosynostosis and

craniofacial disorders) should be cared for by a pediatric neurosurgeon as part of a craniofacial team.

- Infants with hydrocephalus, as well as children and adolescents with complex hydrocephalus, are preferably cared for by a pediatric neurosurgeon; those for whom neuroendoscopy is a surgical option should be evaluated by a pediatric neurosurgeon with neuroendoscopy experience.
- Infants, children, and adolescents with intractable epilepsy who are being considered for seizure surgery should be referred to a neurosurgeon having expertise in seizure surgery.
- Infants and children with infections of the central nervous system, including epidural abscess, subdural empyema, or brain abscess, are preferably cared for by a pediatric neurosurgeon in conjunction with specialists in pediatric infectious disease.
- Infants and children with medical conditions that increase operative risk, such as congenital heart disease, who must undergo a neurosurgical procedure should be cared for by a pediatric neurosurgeon with access to other pediatric specialists.

REFERRAL TO A PEDIATRIC OPHTHALMOLOGY SPECIALIST

A pediatric ophthalmologist has completed a residency in ophthalmology, is certified by the American Board of Ophthalmologic Surgery, and has completed additional training of at least 1 year in pediatric ophthalmology. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years).

Pediatric patients with the following conditions should be referred to a pediatric ophthalmologist:

- children 7 years or younger who are nonverbal or unable to read letters and in whom there is reason to suspect eye disease;
- infants or children with retinoblastoma or other tumors of the eye and orbital area;
- infants or children with known or suspected cataracts, glaucoma, or blindness;
- infants or children with a diagnosis or at risk of retinopathy of prematurity;
- infants or children with congenital or genetic ocular anomalies or infections (eg, aniridia, toxoplasmosis);
- infants or children with systemic syndromes, metabolic disorders, or chromosomal abnormalities with possible ocular involvement (eg, juvenile idiopathic arthritis, galactosemia, diabetes mellitus, Marfan syndrome, Down syndrome); and
- infants or children suspected of being abused and in whom there is a possibility of eye injury.

Pediatric patients with the following conditions are preferably managed by a pediatric ophthalmologist:

- infants with congenital nystagmus and children with early-onset nystagmus;
- children with strabismus or amblyopia (ie, dimness of vision without detectable organic lesion of the eye) or risk factors for strabismus or amblyopia (eg, family history of amblyopia or orbital or eyelid hemangioma);
- children with a family history of congenital or genetic ocular anomalies (eg, aniridia), infections (eg, toxoplasmosis), tumors (eg, retinoblastoma), or a family history of

systemic or metabolic syndromes (eg, juvenile idiopathic arthritis, galactosemia, diabetes mellitus), chromosomal abnormalities (eg, Down syndrome), or other disorders with possible ocular involvement;

- infants or children with exposure during gestation to certain specific drugs or other substances (such as alcohol) that are known to cause anomalies of the eyes;
- infants or children with poor vision or delayed attainment of vision-related developmental milestones and infants and children with severe refractive errors or a strong family history of severe refractive errors; and
- infants or children with ocular or periocular inflammation not responding to initial topical and/or systemic antibiotic therapy or not clearing within 3 weeks of treatment and children with suspected herpes simplex or zoster infections involving the eye or a history of these infections involving the eye.

REFERRAL TO A PEDIATRIC ORTHOPEDIC SURGERY SPECIALIST

A pediatric orthopedic surgeon has completed a residency in orthopedics and completed an additional Accreditation Council for Graduate Medical Education–approved 1-year fellowship in pediatric orthopedics. An orthopedic tumor surgeon has completed a residency in orthopedics, plus additional training in orthopedic oncology, and devotes his or her practice to patients with cancer of the bones and joints. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years).

The following patients may be best cared for by a pediatric orthopedic surgeon:

- infants with malformations of the limbs (eg, idiopathic clubfoot, congenital limb deficiency);
- children and adolescents with significant limb deformity secondary to metabolic bone disease or other types of growth arrest or with significant limb length discrepancy;
- infants, children, and adolescents with developmental dysplasia of the hip (screening for developmental dysplasia of the hip is performed by the primary care pediatrician);
- infants, children, and adolescents with bone or joint infection (eg, osteomyelitis, septic arthritis), in conjunction with the primary care pediatrician and pediatric infectious disease specialist;
- children with Perthes disease (ie, osteochondritis of the femoral head);
- children and adolescents with slipped capital femoral epiphysis;
- infants, children, and adolescents with significant spinal deformity (scoliosis or kyphosis);
- infants, children, and adolescents with disability, deformity, or gait abnormality secondary to neuromuscular conditions (eg, cerebral palsy, spina bifida, muscular dystrophy, spinal muscular atrophy);
- children and adolescents with sports injuries, such as anterior cruciate ligament tears, meniscal tears, cartilage injuries, ankle instability, or shoulder instability;
- adolescents with deformities or sequelae from childhood musculoskeletal disorders;
- infants, children, and adolescents with multiple skeletal trauma or complex fractures and dislocations; and

- children with musculoskeletal extremity or spine injuries who may be victims of nonaccidental trauma.

Malignant bone tumors should be managed by an orthopedic tumor surgeon, in conjunction with a pediatric medical cancer specialist. Benign bone tumors should be managed by a pediatric orthopedic surgeon or an orthopedic tumor surgeon. Congenital deformities or neuromuscular abnormalities of the upper extremity (including obstetrical brachial plexus injuries) should be managed by a pediatric orthopedic surgeon or a pediatric upper extremity surgeon.

REFERRAL TO A PEDIATRIC OTOLARYNGOLOGY SPECIALIST

A pediatric otolaryngologist has completed a 4- to 5-year residency in otolaryngology/head and neck surgery and is certified by the American Board of Otolaryngologic Surgery. In addition, he or she has completed 1 or 2 years of fellowship training in pediatric otolaryngology. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years). The following patients should be referred to a pediatric otolaryngologist, although a pediatric plastic surgeon, pediatric surgeon, pediatric dentist, or pediatric oromaxillofacial surgeon with appropriate education, training, and experience would also be appropriate in some cases:

- infants, children, and adolescents with congenital malformations of head and neck structures, including the ear, nasal passages, oral cavity, and laryngotracheal airway;
- infants and children with sensory impairments, including conductive or sensorineural hearing loss, vestibular disorders, unilateral and bilateral true vocal fold paralysis,

facial nerve paralysis, and oromotor dysfunction as evidenced by speech, swallowing, or drooling problems;

- infants and children with acquired otolaryngologic disorders involving the ear (eg, cholesteatoma), the pharynx, the laryngotracheal airway (eg, postintubation laryngotracheal stenosis), the aerodigestive tract (eg, foreign body aspirations), and the facial skeleton (eg, maxillofacial trauma);
- infants, children, and adolescents with neoplasms or vascular malformations of the head and neck structures, including the laryngotracheal airway;
- infants and children with medical conditions that increase operative risk (eg, congenital heart disease) who must undergo a common otolaryngologic procedure (eg, adenotonsillectomy); and
- infants and children requiring operative airway endoscopy for the evaluation of stridor.

The following patients are preferably managed by a pediatric otolaryngologist:

- infants and children with complicated infections that may require surgery involving the ear (eg, otitis media with effusion and hearing change), the nose and paranasal sinuses (eg, chronic rhinosinusitis), the pharynx (eg, recurrent adenotonsillitis), the airway (eg, epiglottitis), and the neck (eg, retropharyngeal abscess).

REFERRAL TO A PEDIATRIC PLASTIC SURGERY SPECIALIST

A pediatric plastic surgeon is certified by the American Board of Plastic Surgery. He or she has completed the requirements of residency training for board certification in plastic surgery (usually a total of 6 or more years of

surgical and surgical specialty training) plus an additional year training in pediatric plastic surgery and/or pediatric craniofacial surgery, although it is recognized that some general plastic surgeons and occasionally pediatric surgical specialists have the requisite education, training, and experience to deal with some of these problems. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years). Infants, children, and adolescents with congenital malformations of head and neck structures, including the skull (ie, deformational plagiocephaly or craniosynostosis, among others), eyes (ie, micropthalmia, eyelid ptosis), ears (ie, prominent ear deformity, microtia), nose (ie, dermoid lesions, arhinia), mouth (ie, clefts of the lip and palate), and jaws (ie, malocclusion, hemifacial microsomia), should be referred to a pediatric plastic surgeon.

- Infants and children with congenital malformations of the limbs (eg, syndactyly, polydactyly) should be referred to a pediatric plastic surgeon.
- Infants, children, and adolescents with major or significant burns or injuries should be stabilized at a local hospital and then transferred to a pediatric burn/trauma center with a pediatric plastic surgeon as part of the treatment team.
- Infants, children, and adolescents with trauma to the hand, specifically including bone, tendon, and skin injuries, should be referred to a pediatric plastic surgeon.
- Infants, children, and adolescents with large cutaneous pigmented or vascular lesions (eg, nevi, port wine stains, arteriovenous malformations) should be referred to

a pediatric plastic surgeon or other pediatric surgical specialist with the appropriate education, training, and experience.

- Infants, children, and adolescents with large bone or soft tissue tumors that, when excised, leave defects requiring tissue transfer or reconstruction are preferably cared for by a pediatric plastic surgeon.

The pediatric plastic surgeon is optimally part of a multispecialty team (with pediatricians and other pediatric surgical specialists) in management of conditions such as myelomeningocele or complex problems requiring tissue expansion or microsurgical procedures.

REFERRAL TO A PEDIATRIC SURGEON

A pediatric surgeon has completed a 5-year residency training in general surgery, plus a 2-year fellowship in pediatric surgery. He or she is certified by the American Board of Surgery and has further specialized in the surgical treatment of children. The American Board of Surgery now offers a subspecialty certificate in pediatric surgery that can be earned by those Diplomates of the American Board of Surgery who have specialized in pediatric surgery. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years).

- Patients 5 years or younger who may need surgical care should be cared for by a pediatric surgeon.
- Seriously injured infants and children may be stabilized at a local hospital and then should be transferred to a pediatric trauma center.
- Infants, children, and adolescents with solid malignancies should be

cared for from the outset by a pediatric surgeon or pediatric surgical specialist and a pediatric medical cancer specialist.

- Minimally invasive procedures (eg, laparoscopy, thoracoscopy) in infants and children should be performed by a pediatric surgeon trained in these techniques.
- Infants and children with medical conditions that increase operative risk (eg, congenital heart disease, preterm birth) who must undergo a common surgical procedure (eg, hernia repair) should be cared for by a pediatric surgeon.

In the interest of good patient care, it is suggested that a general surgeon who cares for pediatric surgical problems not listed in the above categories should have had a minimum 6-month rotation as a junior or senior resident during his or her general surgical residency on a pediatric surgical service run by a pediatric surgeon. Emphasis in the training rotation should be on surgery in children older than 5 years.

A general surgeon performing surgery in children not listed in the above categories should care for a sufficient number of children annually to maintain a high level of competence and should annually attend pediatric surgery postgraduate courses and meetings.

REFERRAL TO A PEDIATRIC UROLOGIST

A pediatric urologist has completed training in urology, is certified by the American Board of Urology, and has completed a 2-year pediatric urology fellowship. The American Board of Urology now offers a subspecialty certificate in pediatric urology that can be earned by those Diplomates of the American Board of Urology who have specialized in pediatric urology. This

certificate recognizes training and experience in the care of individuals with pediatric urologic conditions of all ages. The development of formal training programs and the availability of subspecialty boards in pediatric urology are relatively recent. Some urologists may have gained a lifetime of pediatric experience, but started practice before such fellowships were available. For purposes of developing these recommendations, the following group definitions are used: infant (0–1 year), child (2–12 years), and adolescent (13–18 years).

- Undescended testicles and elective congenital hydrocele/hernia are optimally corrected in infancy or early childhood; the operation should be performed by a pediatric urologist or surgical specialist.
- Hypospadias is usually repaired in infancy or early childhood; the operation should be performed by a pediatric urologist.
- Complex congenital urologic problems (eg, duplex systems, ureterocele, bladder or cloacal exstrophy, moderate or severe vesicoureteral reflux, posterior urethral valves, or other structural abnormalities of genitourinary development, such as persistent genitourinary sinus or cloacal abnormalities) should preferably be managed by a pediatric urologist.
- Solid malignancies of the kidney, bladder, and testicle should be treated from the outset by a pediatric urologist or surgical specialist in conjunction with a pediatric medical cancer specialist.
- Disorders of sex development should be comanaged from the outset by a pediatric urologist or surgical specialist in conjunction with a management team, which should include a pediatric endocrinologist and a psychologist,

in consultation with the primary care pediatrician.

- Cystoscopic procedures in infants and children preferably should be performed by a pediatric urologist.
- A pediatric urology consultation should be considered when a child has prolonged, severe daytime voiding difficulty.
- A pediatric urologist should be involved in the care of children with spinal cord disorders (eg, myelomeningocele, spinal cord injuries).
- Infants or children with major urologic injuries should be stabilized at the nearest medical center and then transported to a pediatric trauma center.
- Infants or children with testicular torsion should be evaluated at the nearest medical center and undergo surgery promptly.
- When a urinary tract abnormality has been identified prenatally, a pediatric urologist or surgeon should be consulted as a member of the fetal treatment team, preferably prenatally or as early postnatally as is feasible.

REFERRAL FOR ENDOSCOPY

Specialists in several pediatric surgical and pediatric medical fields are

trained to perform endoscopic procedures in infants and children. For purposes of developing these recommendations, the following age group definitions are used: infant (0–1 year) and child (2–12 years).

- Endoscopy of the airways (eg, bronchoscopy, laryngoscopy) in infants and children should be performed by a pediatric surgeon or a pediatric otolaryngologist or an appropriately trained pediatric medical specialist, which may include a pediatric pulmonologist or a pediatric intensivist.
- Esophagoscopy in infants and children should be performed by a pediatric surgeon, a pediatric otolaryngologist, or a pediatric gastroenterologist.
- Endoscopy of the gastrointestinal tract distal to the esophagus (eg, esophagogastroduodenoscopy, colonoscopy) in infants and children should be performed by a pediatric surgeon or a pediatric gastroenterologist.

Because the care of infants, children, and adolescents changes and advances rapidly, these recommendations should be updated at regular intervals.

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School Start Times for Adolescents

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- *Policy Statement*

POLICY STATEMENT

School Start Times for Adolescents

abstract

FREE

The American Academy of Pediatrics recognizes insufficient sleep in adolescents as an important public health issue that significantly affects the health and safety, as well as the academic success, of our nation's middle and high school students. Although a number of factors, including biological changes in sleep associated with puberty, lifestyle choices, and academic demands, negatively affect middle and high school students' ability to obtain sufficient sleep, the evidence strongly implicates earlier school start times (ie, before 8:30 AM) as a key modifiable contributor to insufficient sleep, as well as circadian rhythm disruption, in this population. Furthermore, a substantial body of research has now demonstrated that delaying school start times is an effective countermeasure to chronic sleep loss and has a wide range of potential benefits to students with regard to physical and mental health, safety, and academic achievement. The American Academy of Pediatrics strongly supports the efforts of school districts to optimize sleep in students and urges high schools and middle schools to aim for start times that allow students the opportunity to achieve optimal levels of sleep (8.5–9.5 hours) and to improve physical (eg, reduced obesity risk) and mental (eg, lower rates of depression) health, safety (eg, drowsy driving crashes), academic performance, and quality of life. *Pediatrics* 2014;134:642–649

FACTORS INFLUENCING INSUFFICIENT SLEEP IN ADOLESCENTS

Insufficient sleep represents one of the most common, important, and potentially remediable health risks in children,^{1,2} particularly in the adolescent population, for whom chronic sleep loss has increasingly become the norm.³ The reasons behind the current epidemic of insufficient sleep are complex and interrelated. From a biological perspective, at about the time of pubertal onset, most adolescents begin to experience a sleep–wake “phase delay” (later sleep onset and wake times), manifested as a shift of up to 2 hours relative to sleep–wake cycles in middle childhood.⁴ Two principal biological changes in sleep regulation are thought to be responsible for this phenomenon.^{5,6} One factor is delayed timing of nocturnal melatonin secretion across adolescence^{5,7,8} that parallels a shift in circadian phase preference from more “morning” type to more “evening” type, which consequently results in difficulty falling asleep at an earlier bedtime.⁴ The second biological factor is an altered “sleep drive” across adolescence, in which the pressure to fall asleep accumulates more slowly, as demonstrated by the adolescent brain's response to sleep loss⁹

ADOLESCENT SLEEP WORKING GROUP, COMMITTEE ON ADOLESCENCE, and COUNCIL ON SCHOOL HEALTH

KEY WORDS

adolescents, insufficient sleep, school start times

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and by a longer time to fall asleep after being awake for 14.5 to 18.5 hours in postpubertal versus prepubertal teenagers.¹⁰ Thus, these 2 factors typically make it easier for adolescents to stay awake later. At the same time, several studies from different perspectives indicate that adolescent sleep needs do not decline from preadolescent levels, and optimal sleep for most teenagers is in the range of 8.5 to 9.5 hours per night.^{5,11,12} On a practical level, this research indicates that the average teenager in today's society has difficulty falling asleep before 11:00 PM and is best suited to wake at 8:00 AM or later.^{4,12,13}

The sleep–wake changes that flow from this biological maturation may enable teenagers' interactions with such environmental factors and lifestyle/social demands as homework, extra-curricular activities, after-school jobs, and use of technology.^{14–16} As a result, most teenagers stay up late on school nights, getting too little sleep, and then sleep in on weekends to “catch up” on sleep. Although this weekend oversleeping can help offset the weekly sleep deficit, it can worsen circadian disruption and morning sleepiness at school.^{9,17,18}

The Extent and Effects of Adolescent Sleep Loss

Given both biological demands and today's sociocultural influences, it is not surprising that many studies have documented that the average adolescent in the United States is chronically sleep deprived and pathologically sleepy (ie, regularly experiencing levels of sleepiness commensurate with those of patients with sleep disorders such as narcolepsy).¹⁹ For example, a recent National Sleep Foundation poll²⁰ found that 59% of sixth- through eighth-graders and 87% of high school students in the United States were getting less than the recommended 8.5 to 9.5 hours of sleep on school

nights; indeed, the average amount of school night sleep obtained by high school seniors was less than 7 hours. In this same survey, however, 71% of parents believed that their adolescent was obtaining sufficient sleep. This mismatch indicates a significant lack of awareness among adults regarding the extent of adolescent sleep loss. As a result, many middle and high school students are at risk for adverse consequences of insufficient sleep, including impairments in mood, affect regulation, attention, memory, behavior control, executive function, and quality of life (Table 1).^{21–26}

Insufficient sleep also takes a toll on academic performance. In the National Sleep Foundation poll cited previously,²⁰ 28% of students reported falling asleep in school at least once a week, and more than 1 in 5 fell asleep doing homework with similar frequency. Many studies show an association between decreased sleep duration and lower academic achievement at the middle school, high school, and college levels, as well as higher rates of absenteeism and tardiness and decreased readiness to learn (Table 1).^{17,27–30}

An increased prevalence of anxiety and mood disorders has also been linked to poor quality and insufficient sleep in adolescents.^{31–33} Other specific health-related effects of sleep loss include increased use of stimulants (eg, caffeine, prescription medications) to counter the effects of chronic sleepiness on academic performance.^{34,35} Adolescents are also at greater risk of drowsy driving–related crashes as a result of insufficient sleep.^{36,37} Chronic sleep restriction increases subsequent risk of both cardiovascular disease and metabolic dysfunction, such as type 2 diabetes mellitus.^{38,39} An association between short sleep duration and obesity in children and adolescents has been demonstrated in several cross-sectional and prospective

studies, underscoring how chronic sleep restriction can undermine health (Table 1).^{40,41}

IDENTIFYING SOLUTIONS: THE ROLE OF DELAYING SCHOOL START TIMES

This “epidemic” of delayed, insufficient, and erratic sleep patterns among adolescents and the accompanying negative effects on adolescent health and well-being highlight the importance of identifying potentially modifiable factors. The quest to reduce the high cost of sleep loss in adolescents is not only an important public health issue but one of paramount importance to educators, pediatric health care providers, and

TABLE 1 Impact of Chronic Sleep Loss in Adolescents

Physical health and safety
Increased obesity risk
Metabolic dysfunction (hypercholesterolemia, type 2 diabetes mellitus)
Increased cardiovascular morbidity (hypertension, increased risk of stroke)
Increased rates of motor vehicle crashes (“drowsy driving”)
Higher rates of caffeine consumption; increased risk of toxicity/overdose
Nonmedical use of stimulant medications; diversion
Lower levels of physical activity
Mental health and behavior
Increased risk for anxiety, depression, suicidal ideation
Poor impulse control and self-regulation; increased risk-taking behaviors
Emotional dysregulation; decreased positive affect
Impaired interpretation of social/emotional cues in self and others
Decreased motivation
Increased vulnerability to stress
Academics and school performance
Cognitive deficits, especially with more complex tasks
Impairments in executive function (working memory, organization, time management, sustained effort)
Impairments in attention and memory
Deficits in abstract thinking, verbal creativity
Decreased performance efficiency and output
Lower academic achievement
Poor school attendance
Increased dropout rates

advocates for adolescent health. Although many changes over the course of adolescence can affect the quality and quantity of sleep, one of the most salient and, arguably, most malleable is that of school start times. Numerous studies have demonstrated that early start times impede middle and high school students' ability to get sufficient sleep. Studies comparing high schools with start times as little as 30 minutes earlier versus those with later start times demonstrate such adverse consequences as shorter sleep duration, increased sleepiness, difficulty concentrating, behavior problems, and absenteeism.^{29,30,42–46} For example, in one key school transition study, Carskadon et al¹⁹ evaluated the effects of a 65-minute advance (ie, move earlier) in school start time from grade 9 to grade 10 in 40 students. They found a delay in the biological markers of circadian timing but also objectively measured daytime sleepiness levels typical of patients with sleep disorders. Because circadian-based phase delays emerge at around the time of pubertal onset, they also affect younger adolescents, who increasingly are subject to many of the same environmental and lifestyle competing priorities for sleep as older teenagers. Recent research shows that delaying school start times for middle school students is accompanied by positive outcomes similar to those found in high schools, including later rise times, more school night total sleep, less daytime sleepiness, decreased tardiness rates, improved academic performance, and better performance on computerized attention tasks.^{30,47,48}

According to the US Department of Education statistics for 2011–2012,⁴⁹ approximately 43% of the over 18 000 public high schools in the United States currently have a start time before 8:00 AM. Over the last 15 years, however, a small but growing number of

school districts have responded to research reports regarding insufficient sleep among middle and high school students with what may be viewed as a “systematic countermeasure” to reduce the prevalence of sleepiness and its consequences: delaying school start times. Early studies addressed a core question: “Does delaying start time result in students obtaining more sleep, or do students just stay up later and thus negate the effects of the delayed start time?” Wahlstrom et al^{50,51} assessed more than 18 000 high school students in Minneapolis before and after the district's school start time changed from 7:15 AM to 8:40 AM beginning with the 1997–1998 school year. Bedtimes after the change were similar (ie, did not shift to a later time) to those of students in schools that did not change start times, and, as a result, students obtained nearly 1 additional hour of sleep on school nights during the 1999–2000 school year. Other studies have also failed to show a delay in bedtime in response to delayed start times. In a study involving grades 6 through 12 in a school district that delayed high school start times by 1 hour (7:30 to 8:30 AM), students averaged 12 to 30 minutes more nightly sleep, and the percentage of students who reported ≥ 8 hours of sleep increased from 37% to 50%.⁵² Owens et al,⁵³ in a study of adolescents attending an independent school that instituted a start time delay of 30 minutes (from 8:00 to 8:30 AM), reported that average bedtimes actually shifted *earlier* by an average of 18 minutes, and mean self-reported school night sleep duration increased by 45 minutes. In addition, the percentage of students getting less than 7 hours of sleep decreased by 79%, and those reporting at least 8 hours of sleep increased from 16% to 55%. Finally, in a 3-year study of >9000 students from 8 public high schools in 3 states (Colorado, Wyoming, and Minnesota),

the percentage of students sleeping ≥ 8 hours per night was dramatically higher in those schools that had a later start time (eg, 33% at 7:30 AM vs 66% at 8:55 AM).⁵⁴

Moreover, a number of studies have now clearly demonstrated that delaying school start times not only results in a substantive increase in average sleep duration but also has a significant positive effect on a variety of key outcomes; these effects range from decreased levels of self-reported sleepiness and fatigue to improvements in academic measures. In the Minneapolis study,^{50,51} attendance rates for students in grades 9 through 11 improved, and the percentage of high school students continuously enrolled increased. Likewise, Dexter et al⁴² found that public high school sophomores and juniors at a later- versus earlier-starting high school reported more sleep and less daytime sleepiness. Htwe et al⁵⁵ reported that high school students slept an additional 35 minutes, on average, and experienced less daytime sleepiness after their school start time was delayed from 7:35 to 8:15 AM.

Improvements in academic achievement associated with delayed start times have been somewhat less consistently demonstrated; in the Minneapolis study, grades showed a slight but not statistically significant improvement,⁵⁰ and standardized test scores were not increased overall compared with those before the start time change.^{46,56} However, several recent studies have documented improvements in academic performance associated with later start times. A study of students in Chicago public high schools demonstrated that absences were much more common and student grades and test score performance were notably lower for first-period classes compared with afternoon classes and that performance on end-of-year

subject-specific standardized tests (ie, math, English) correlated with whether the student was scheduled for that subject during first period.⁵⁶ Similarly, first-year Air Force Academy students assigned to start classes after 8:00 AM (compared with before 8:00 AM) performed better in their first-period course and, in addition, had a 0.15 SD increase in performance across all of their courses.⁴⁴ In a study focusing on middle school students,⁴⁵ a 1-hour later shift in school start times was associated with an increase in reading test scores by 0.03 to 0.10 SD and in math test scores by 0.06 to 0.09 SD. The author concluded that an increase in start times by 1 hour would result in a 3 percentile point gain in both math and reading test scores for the average student. Furthermore, students performing in the lower end of the test score distribution seemed to benefit most, with gains roughly twice those in above-average students, and the effects persisted into high school. In a more recent middle school study by the same research group, the results suggested that moving school start later by 1 hour can have an impact on standardized test scores comparable to decreasing the class size by one-third. Finally, in a recent 3-state study, 5 of the 6 high schools in which grade point average was assessed showed a significant pre-post increase in grade point average in core subjects of math, English, science, and social studies.⁵⁴

Finally, there may be additional health-related and other benefits associated with delays in start time. For example, students in the independent school study cited previously⁵³ reported significantly more satisfaction with their sleep. In addition, class attendance improved, as did health-related variables, including fewer visits to the campus health center for fatigue-related complaints.⁵³ Although not specifically

assessed as an outcome in previous research, later start times might increase the likelihood that students will eat breakfast before school and thus further enhance their readiness to learn.⁵⁷ Finally, improvements in teacher satisfaction linked to increased sleep offers yet another potential mechanism for classroom enrichment.

Several other outcome measures examined in these studies also deserve emphasis. In the study by Owens et al,⁵³ there were significantly fewer students self-reporting symptoms of depressed mood as well as improved motivation after the start time delay. In a more recent study, also conducted in an independent school setting, a 25-minute delay in start time was associated not only with increased sleep duration and decreased daytime sleepiness but also with less self-reported depressed mood.⁵⁸ Although more research is needed, given the mounting evidence supporting a bidirectional link between sleep patterns and problems and mood disorders in this population⁵⁹ (including an increased risk of suicidal ideation⁵⁷), countermeasures that could potentially mitigate these effects have important public health implications.

Furthermore, adolescents are at particularly high risk of driving while impaired by sleepiness, and young drivers aged 25 years or younger are involved in more than one-half of the estimated 100 000 police-reported, fatigue-related traffic crashes each year.⁶⁰ Danner and Phillips⁵² examined the relationship between automobile crash records for students 17 to 18 years of age and high school start times. Car crash rates for the county that delayed school start times decreased by 16.5% over the 2 years before and after the school-start change, whereas those for the state as a whole increased by 7.8% across the same time period. In another recent study conducted in

2 adjacent, demographically similar cities, there were significantly increased teen (16- to 18-year-olds) crash rates over a 2-year period in the city with earlier high school start times (2007: 71.2 per 1000 vs 55.6 per 1000; 2008: 65.8 per 1000 vs 46.6 per 1000 [$P < .001$]), and teen drivers' morning crash peaks occurred 1 hour earlier.⁶¹ Finally, the recent study by Wahlstrom et al⁵⁴ found a crash rate reduction in 16- to 18-year-olds of 65% and 70%, respectively, in 2 of the 4 high schools studied; notably, the high school with the latest start time (Jackson Hole, WY) had the largest decline in car crashes.

Although considerable empiric support exists for the concepts that early school start times are detrimental to adolescents' health and well-being and that delaying school start times results in substantive and sustained benefits to students, the ongoing debate among school districts in the United States regarding the widespread institution of later start times for middle and high schools continues to spark controversy. Moreover, the logistical considerations in implementing delayed school start times in middle and high schools are far from trivial. Wolfson and Carskadon⁶² surveyed 345 public high school personnel regarding their perspective on high school start times, factors influencing school start times, and decision-making around school schedules. Most respondents at that time had not changed or contemplated changing their school start times. Perceived barriers to changing school schedules commonly endorsed included curtailed time for athletic practices and interference with scheduling of games, reduced after-school employment hours for students, challenges in providing child care for younger siblings, adjustments in parent and family schedules, potential safety issues, effects on sleep duration in younger children if

elementary school schedules are “flipped” with those of middle/high school students, and the need to make alternative transportation arrangements. However, to date, to our knowledge, there have been no published studies that have systematically examined the impact of school start time delay on these parameters, although anecdotal evidence suggests that many of these concerns are unfounded (www.sleepfoundation.org). Moreover, communities across the country have adopted a variety of creative solutions to address these problems, including shifting to public transportation for older students, enlisting community volunteers to provide supervision at bus stops, adjusting class schedules to minimize late dismissal times, scheduling free periods/study halls at the end of the school day to allow participation in after-school extracurricular activities, exempting student athletes from physical education requirements, and installing lights for athletic fields.

In addition, as outlined in a recent Brookings Institute Report (“Organizing Schools to Improve Student Achievement: Start Times, Grade Configurations, and Teacher Assignments”),⁶³ economists have suggested that delaying school start times would have a substantial benefit-to-cost ratio (9:1). This finding is based on a conservative estimate of both costs per student (\$0–\$1950, largely related to transportation) and the increase in projected future earnings per student in present value because of test score gains related to moving start times 1 hour later (approximately \$17 500). Finally, because the appropriation of federal dollars for schools is partially dependent on student attendance data, reducing tardiness and absenteeism levels could result in increased funding and further offset costs related to moving start times later.

CONCLUSIONS

Taken together, these studies support the presence of significant improvements in benchmarks of health and academic success in a variety of settings in association with later school start times, including in urban school districts with a large percentage of low-income and minority students, suburban public schools, and college-preparatory independent schools. It is clear that additional research is needed to further document the effects of changes in school start times over time, to examine specific factors that increase or decrease the likelihood of positive outcomes, and to assess the effect on families, the community, other stakeholders, and the educational system in general. However, it may be strongly argued that both the urgency and the magnitude of the problem of sleep loss in adolescents and the availability of an intervention that has the potential to have broad and immediate effects are highly compelling.

It should also be emphasized that delaying school start times alone is less likely to have a significant effect without concomitant attention to other contributing and potentially remediable factors, such as excessive demands on students’ time because of homework, extracurricular activities, after-school employment, social networking, and electronic media use. One of the biggest challenges school districts face is the need to inform community stakeholders (eg, parents, teachers and administrators, coaches, students, bus drivers, businesses that employ students, law enforcement officials) about the scientific rationale underpinning the merits of delaying school start times; the threats to health, safety, and academic success posed by insufficient sleep; and the potential benefits for adolescents of school start time delay. Thus, education and community engagement are equally

key components in increasing the likelihood of success.

The American Academy of Pediatrics recognizes insufficient sleep in adolescents as a public health issue, endorses the scientific rationale for later school start times, and acknowledges the potential benefits to students with regard to physical and mental health, safety, and academic achievement. The American Academy of Pediatrics lends its strong support to school districts contemplating delaying school start times as a means of optimizing sleep and alertness in the learning environment and encourages all school administrators and other stakeholders in communities around the country to review the scientific evidence regarding school start times, to initiate discussions on this issue, and to systematically evaluate the community-wide impact of these changes (eg, on academic performance, school budget, traffic patterns, teacher retention).

RECOMMENDATIONS

1. Pediatricians should educate adolescents and parents regarding the optimal sleep amount teenagers need to match physiologic sleep needs (8.5–9.5 hours). Although napping, extending sleep on weekends, and caffeine consumption can temporarily counteract sleepiness, these measures do not restore optimal alertness and are not a substitute for regular sufficient sleep.
2. Health care professionals, especially those working in school-based clinics or acting in an advisory capacity to schools, should be aware of adolescent sleep needs. They should educate parents, teenagers, educators, athletic coaches, and other stakeholders about the biological and environmental factors, including early school start times, that contribute to widespread chronic sleep deprivation in America’s youth.

3. Educational interventions for parents and adolescents as well as the general public should be developed and disseminated by the American Academy of Pediatrics and other child and sleep health advocacy groups. Content should include the potential risks of chronic sleep loss in adolescents, including depressed mood, deficits in learning, attention and memory problems, poor impulse control, academic performance deficits, an increased risk of fall-asleep motor vehicle crashes, and an elevated risk of obesity, hypertension, and long-term cardiovascular morbidity. Information should also be included about the potential utility of systemic countermeasures, including delaying school start times, in mitigating these effects. Finally, educational efforts should also emphasize the importance of behavior change on the individual level and the personal responsibility that families and students themselves have in modifying their sleep habits.
4. Pediatricians and other pediatric health care providers (eg, school physicians, school nurses) should provide scientific information, evidence-based rationales, guidance, and support to educate school administrators, parent-teacher associations, and school boards about the benefits of instituting a delay in start times as a potentially highly cost-effective countermeasure to adolescent sleep deprivation and sleepiness. In most districts, middle and high schools should aim for a starting time of no earlier than 8:30 AM. However, individual school districts also need to take average commuting times and other exigencies into

account in setting a start time that allows for adequate sleep opportunity for students. Additional information regarding opportunities, challenges, and potential solutions involved in changing school start times may be found at: <http://www.sleepfoundation.org/article/sleep-topics/school-start-time-and-sleep>; <http://schoolstarttime.org>.

5. Pediatricians should routinely provide education and support to adolescents and families regarding the significance of sleep and healthy sleep habits as an important component of anticipatory guidance and well-child care. In particular, pediatricians should endorse parental involvement in setting bedtimes and in supervising sleep practices, such as social networking and electronic media use in the bedroom; for example, pediatricians could recommend to parents that they establish a “home media use plan” and enforce a “media curfew.” Adolescents should be regularly queried regarding sleep patterns and duration and counseled about the risks of excessive caffeine consumption, misuse of stimulant medications as a countermeasure to sleepiness, and the dangers of drowsy driving.

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Screening for Nonviral Sexually Transmitted Infections in Adolescents and Young Adults

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- *Policy Statement*

POLICY STATEMENT

Screening for Nonviral Sexually Transmitted Infections in Adolescents and Young Adults

abstract

FREE

Prevalence rates of many sexually transmitted infections (STIs) are highest among adolescents. If nonviral STIs are detected early, they can be treated, transmission to others can be eliminated, and sequelae can be averted. The US Preventive Services Task Force and the Centers for Disease Control and Prevention have published chlamydia, gonorrhea, and syphilis screening guidelines that recommend screening those at risk on the basis of epidemiologic and clinical outcomes data. This policy statement specifically focuses on these curable, nonviral STIs and reviews the evidence for nonviral STI screening in adolescents, communicates the value of screening, and outlines recommendations for routine nonviral STI screening of adolescents. *Pediatrics* 2014;134:e302–e311

EVIDENCE TO SUPPORT NONVIRAL STI SCREENING

The goal of sexually transmitted infection (STI) screening is to identify and treat individuals with treatable infections, reduce transmission to others, avoid or minimize long-term consequences, identify other exposed and potentially infected individuals, and decrease the prevalence of infection in a community. Healthy People 2020 objectives for sexually transmitted diseases¹ include items that address screening for chlamydia in sexually active females younger than 25 years and set targets for decreased rates of chlamydia, gonorrhea, and syphilis in specific populations. The US Preventive Services Task Force (USPSTF), an independent panel of prevention and evidence-based medicine experts, has published chlamydia,² gonorrhea,³ and syphilis^{4,5} screening guidelines that recommend screening those at risk on the basis of epidemiologic and clinical outcomes data. The Centers for Disease Control and Prevention (CDC) publishes evidence-based STI screening recommendations for specific at-risk populations that are not addressed by the USPSTF but that pose public health challenges for disease prevention and control.^{6–8} Major professional medical organizations, including the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians, have also published STI screening guidelines for specific populations.^{7–10} The American Academy of Pediatrics' (AAP) Bright Futures guidelines for health supervision recommend chlamydia and gonorrhea screening as appropriate for the patient population and the clinical setting.¹¹ Recent AAP clinical reports addressing gynecologic examinations and male reproductive and sexual health care discuss clinic issues and provider

COMMITTEE ON ADOLESCENCE and SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE

KEY WORDS

sexually transmitted infections, nonviral STIs, chlamydia, gonorrhea, syphilis, screening

ABBREVIATIONS

AAP—American Academy of Pediatrics
 CDC—Centers for Disease Control and Prevention
 CLIA—Clinical Laboratory Improvement Amendment
 FDA—Food and Drug Administration
 MSM—males who have sex with males
 NAAT—nucleic acid amplification test
 PID—pelvic inflammatory disease
 STI—sexually transmitted infection
 USPSTF—US Preventive Services Task Force

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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skills that are relevant to office-based screening for nonviral STIs.^{12,13} These clinical reports and CDC recommendations⁶ describe the important elements of a sexual history. The goal of this policy statement is to review the evidence in support of nonviral STI screening in adolescents and to educate pediatricians about the value of screening as well as resources available to support this practice. Screening considerations from the CDC specific to pregnant and HIV-infected individuals should be reviewed (www.cdc.gov/std/treatment).⁶ Guidance about how to incorporate chlamydia screening into the office setting including addressing confidentiality, billing, and explanation of benefits statements can be found at the National Chlamydia Coalition Web site (<http://ncc.prevent.org/info/healthcare-providers>). This site provides a link to up-to-date resources and a monograph titled *Why Screen for Chlamydia; An Implementation Guide for Healthcare Providers*. The AAP policy statement addressing standards for Health Information Technology to ensure adolescent privacy may be useful in the establishment of practice procedures and help anticipate questions regarding confidentiality.¹⁴

CHLAMYDIA

Importance

Chlamydia trachomatis is the most common reportable communicable disease in the United States, with the highest case rates occurring in female 20- to 24-year-olds followed closely by rates in female 15- to 19-year-olds.⁸ Chlamydia is common among all races and ethnic groups; however, large racial disparities in chlamydial burden exist, and young women and men of color are disproportionately affected.^{8,15} Among sexually active female 15- to 19-year-olds, chlamydia prevalence among non-Hispanic African Americans is more

than 5 times the prevalence among non-Hispanic whites (7719/100 000 population vs 1458/100 000).⁸ In male 15- to 19-year-olds, in whom the rates have increased every year since 2006, the rate of chlamydia infection among non-Hispanic African Americans is 10 times the rate in non-Hispanic whites (2334/100 000 population vs 236/100 000).⁸ Rates for American Indian/Alaskan Native and Hispanic populations are between the rates for African American and white populations.

Most chlamydia infections are asymptomatic and may persist if left untreated. Previous infection does not confer any clinically reliable protective immunity.¹⁶ Vaccines are not available for chlamydia or for any of the subsequently discussed nonviral STIs. Chlamydia can manifest as cervicitis, urethritis, proctitis, and uncommonly, pharyngitis. Complications and sequelae may include pelvic inflammatory disease (PID), tubal-factor infertility, ectopic pregnancy,^{6,17} chronic pelvic pain,¹⁸ increased HIV transmission,^{19–23} adverse pregnancy and infant outcomes,²⁴ neonatal infections,²⁵ epididymitis,²⁶ and reactive arthritis.^{16,27}

Background

The USPSTF, AAP, and American Academy of Family Physicians recommend annual chlamydia screening of all sexually experienced females younger than 25 years. The CDC and American College of Obstetricians and Gynecologists recommend annual routine screening of sexually experienced females through the age of 25 years. The National Commission on Prevention Priorities ranked chlamydia screening of young women as 1 of the 10 most beneficial and cost-effective preventive services but also among the most underutilized.²⁸

The USPSTF found insufficient evidence to recommend for or against routine chlamydia screening of young men.

Because the risk of complications or long-term reproductive sequelae for chlamydia-infected males is low, screening asymptomatic males does not offer substantial secondary prevention for them. In addition, male older adolescents/young adults are less likely than their female counterparts to use health care services and thus may be difficult to reach with a chlamydia screening program.²⁹ However, the CDC recommends considering screening young men in clinical settings with high chlamydia prevalence rates, such as jails or juvenile corrections facilities, national job training programs, and STD, high school, or adolescent clinics, when resources permit.^{6,30} Males in these settings with a history of multiple partners are at greatest risk of asymptomatic chlamydia infection.^{31–33} The CDC also recommends chlamydia screening of males who have sex with males (MSM) at least annually for urethral and rectal infection on the basis of reported sexual practices and every 3 to 6 months if considered high risk because of multiple or anonymous partners, sex in conjunction with illicit drug use, or having sex partners who participate in these activities.⁶ Sex partners of chlamydia-infected individuals during the 60 days before the diagnosis should also be targeted for testing and treatment because of their high likelihood of infection.⁶

Laboratory Testing

Detection of genitourinary chlamydia infections has substantially improved over the past 2 decades. Nucleic acid amplification tests (NAATs) are preferred for *C trachomatis* detection in adolescents and young adults, regardless of symptoms.³⁴ *C trachomatis* NAATs are sensitive and specific and licensed for use with urine, urethral, vaginal, and cervical specimens. Many of the chlamydia NAATs are approved by the Food and Drug Administration

(FDA) to test patient-collected vaginal swabs in the clinical setting and liquid cytology specimens.^{34,35} Among all of the aforementioned specimens, female vaginal swab specimens and male first-void urine are considered the optimal specimen types.³⁴ Female urine remains an acceptable chlamydia NAAT specimen but may have slightly reduced performance compared with cervical or vaginal swab specimens.³⁴ The CDC recommends at least an annual urine chlamydial NAAT for urethral infection for MSM who have had insertive anal intercourse and an annual rectal swab chlamydial NAAT for those who have had receptive anal intercourse.⁶ Although chlamydia NAATs are not approved by the FDA for rectal swab specimen testing, laboratories that have met Clinical Laboratory Improvement Amendment (CLIA) and other regulatory requirements and validated chlamydia NAAT performance on rectal swab specimens may perform these tests.^{6,34,36} In the evaluation of the sexual assault victim, NAATs may be used for female vaginal swab and urine specimens. Some jurisdictions may prefer *C. trachomatis* culture from all sites in lower-prevalence populations because of greater specificity, although sensitivity may be compromised.⁶

Disease-Specific Benefits and Risks of Screening

In randomized clinical trials, screening asymptomatic sexually active young women for chlamydia and treating those identified with infection reduced the risk of subsequent PID.^{37,38} Other studies, summarized by Haggerty et al, support the association of repeated chlamydia infection with increased reproductive sequelae.¹⁸

Clinical Considerations

Because reinfection is common, providers should rescreen all male and

female patients treated for chlamydia approximately 3 months after treatment. If retesting at 3 months is not possible, retest whenever patients next present for health care services in the 12 months after the initial treatment. A systems-based approach of collecting a noninvasive specimen on all females before they are seen by the health care provider, such as during nursing triage, enhances the proportion of sexually active females who are screened.^{39–41} The National Chlamydia Coalition produces resources for health care providers to facilitate office-based chlamydia screening.⁴² Internet-based interventions to promote chlamydia screening with self-collected vaginal swab specimens in various nonclinical settings are also being evaluated.^{43,44}

GONORRHEA

Importance

Gonorrhea is the second most common reportable communicable disease in the United States; female 20- to 24-year-olds have the highest and female 15- to 19-year-olds the second highest reported gonorrhea case rates compared with any other age or gender.⁸ Substantial racial disparity exists for gonorrhea. The 2012 reported rates among male and female non-Hispanic African American 15- to 19-year-olds are 26 times and 15 times those of male and female non-Hispanic white 15- to 19-year-olds, respectively.⁸ A recent study has shown that residential segregation of black populations contributes to the large racial disparity for youth by creating distinct social networks that perpetuate the persistence of their endemically high gonorrhea rates.⁴⁵ Rates for American Indian/Alaskan native and Hispanic populations are between the rates for non-Hispanic African American and non-Hispanic white populations.

As with *C. trachomatis*, many infections are asymptomatic, and *Neisseria gonorrhoeae* can cause cervicitis, urethritis, proctitis, and pharyngitis. On occasion, gonorrhea may also lead to conjunctivitis.⁴⁶ Uncomplicated gonorrhea infection can spread to the upper genital tract, causing PID and associated longer-term complications, such as ectopic pregnancy, infertility, and chronic pelvic pain in females and epididymitis in males, and hematogenous spread can cause disseminated gonococcal infection. Gonorrhea infection is also associated with increased HIV transmission.⁴⁷ In pregnancy, gonorrhea is associated with chorioamnionitis, premature rupture of membranes, and preterm labor. Perinatal transmission can lead to ophthalmia neonatorum. Rarely, newborn infants develop life-threatening systemic disease from gonorrhea acquired during delivery through an infected birth canal.²⁵

Background

The USPSTF recommends annual gonorrhea screening of all at-risk, sexually active females.³ Populations at highest risk of gonorrhea infection include females and males younger than 25 years and individuals with a history of previous gonorrhea infection, other STIs, new or multiple sex partners, inconsistent condom use, or who engage in sex work or drug use. The USPSTF found insufficient evidence to recommend for or against routine gonorrhea screening of asymptomatic males because of the low prevalence rates and the lower rates of morbidity related to untreated gonorrhea infection in males and because asymptomatic infection is less common in males than in females.

The CDC recommends urethral, rectal, and oropharyngeal gonorrhea testing at least annually for MSM who engage in receptive anal or oral intercourse, respectively, as well as urine-based

testing at least annually for MSM engaging in insertive anal or oral intercourse.^{6,34,48} The CDC also recommends gonorrhea screening every 3 to 6 months for MSM who are at higher risk because of multiple or anonymous partners, sex in conjunction with illicit drug use (especially methamphetamines), or partners who participate in these activities.^{6,49,50}

Sex partners of gonorrhea-infected individuals during the 60 days before gonorrhea diagnosis should be targeted for testing and treatment because of their high likelihood of infection.⁶ Because gonorrhea rates vary widely by communities and population, health care providers should consider local gonorrhea epidemiology to determine if gonorrhea screening in male adolescents is appropriate in their patient population.

Laboratory Testing

Recent shifts have occurred in *N gonorrhoeae* screening options. NAATs are recommended for detection of genitourinary gonococcal infections in males and females, regardless of symptoms.^{6,34} Gonorrhea and chlamydia NAATs are usually available as combination tests from a single specimen. Like those for chlamydia, *N gonorrhoeae* NAATs have high sensitivity and specificity. Most are approved by the FDA for use with urine and urethral, vaginal, and cervical swab specimens in the clinical setting. Some gonorrhea NAATs are also licensed to test patient-collected vaginal swab specimens in a clinical setting and liquid cytology specimens. Among all specimens, female vaginal swab specimens and male urine are the optimal specimen types.³⁴

Although gonorrhea NAATs are not approved by the FDA for extragenital sites, many laboratories have met CLIA and other regulatory requirements and validated gonorrhea NAAT testing on

rectal and pharyngeal specimens.^{34,36,51} NAATs cannot be used to determine gonorrhea antimicrobial resistance; thus, culture must be obtained to identify antibiotic-resistant gonorrhea strains,^{8,34} although it has lower sensitivity especially at extragenital sites compared with NAATs. Ideally, gonorrhea culture is needed for evaluating suspected cases of treatment failure, for test of cure for patients who were treated with an alternative regimen, and for investigating suspected childhood sexual abuse or assault.⁶

Disease-Specific Benefits and Risks of Screening

Identification of gonorrhea infection allows for treatment, prevention of sequelae, and identification of exposed partners; reduces further transmission to others; and may be a marker or risk factor for HIV transmission.

Clinical Considerations

Providers should rescreen all male and female patients treated for gonorrhea approximately 3 months after treatment at the anatomic site of infection because reinfection is common. Gonorrhea treatment is challenging because of the organism's ability to readily develop antimicrobial resistance.^{6,8,52,53} The possibility of emerging cephalosporin-resistant *N gonorrhoeae* is a growing concern.⁴⁸ The CDC's Gonococcal Isolate Surveillance Project has documented recent trends of decreasing cephalosporin susceptibility among *N gonorrhoeae*.⁵² Cases of suspected gonorrhea treatment failures should be reported to local or state health departments, and a gonococcal culture of specimens from exposed sites, preferably with simultaneous NAAT and antimicrobial-susceptibility testing, should be performed if *N gonorrhoeae* is isolated.⁶ Patients with a diagnosis of uncomplicated urogenital or rectal gonorrhea who are treated with any of the

recommended or alternative regimens do not need a test-of-cure.⁶ However, patients with pharyngeal gonorrhea who are treated with an alternative regimen should return 14 days after treatment of a test-of-cure, using either culture or NAAT.⁶ If the NAAT is positive, every effort should be made to perform a confirmatory culture.

TRICHOMONIASIS

Importance

Trichomonas vaginalis infection is not a nationally reportable communicable disease; however, *T vaginalis* genital tract infection is believed to be the most common nonviral STI on the basis of population studies.⁵⁴ Unlike chlamydia and gonorrhea infections, which are most common among female adolescents and young adults, trichomoniasis is also common among older females. In adolescent female samples, *T vaginalis* prevalence rates have ranged from 2.1% to 14.4%.^{54–57} Although this infection is commonly asymptomatic in females, *T vaginalis* infection has been associated with vaginitis and PID.^{25,58,59} In some cases, it may cause preterm labor^{60–62} and may increase HIV transmission.^{63,64} The majority of infections (approximately 80%) are also asymptomatic in males, although *T vaginalis* can cause urethritis, epididymitis, and prostatitis.^{65–67} Similar to other STIs, a substantial racial disparity exists, with prevalence rates 10 times higher among female non-Hispanic African Americans compared with their non-Hispanic white and Mexican American counterparts.⁵⁴

Background

Although the USPSTF has not published *T vaginalis* screening recommendations, CDC recommends screening HIV-infected females for *T vaginalis* annually and suggests that screening can be considered in females at high risk of infection, including those with new or multiple

partners, those with a history of STIs, and those who exchange sex for payment or inject drugs.⁶

Laboratory Testing

T vaginalis is often identified through microscopic examination of vaginal secretions on a slide preparation (ie, “wet mount”). This method requires immediate viewing for optimal results and has poor sensitivity (approximately 60%–70%).^{64,68,69} Consequently, false-negative results are common with microscopic identification, and true infections may be underrecognized and undertreated.^{68,70,71} Clinical laboratory tests with greater sensitivity compared with wet mount include trichomonas culture in Diamond media or other trichomoniasis-specific culture systems (eg, InPouch, BioMed Diagnostics, White City, OR); a CLIA-waived, antigen-detection, point-of-care test (OSOM, Sekisui Diagnostics, Exton, PA); and a nucleic acid probe test (Affirm VPIII, Becton, Dickinson and Company, Franklin Lakes, NJ) for *T vaginalis*, *Gardnerella vaginalis*, and *Candida albicans*. A NAAT for *T vaginalis* (APTIMA; GenProbe, San Diego, CA) is available and licensed for use with female cervical or vaginal swab, urine, and PreservCyt Solution specimens. A routine Papanicolaou test should not be used to diagnose *T vaginalis* infection because of poor sensitivity and specificity.⁶ The *T vaginalis* NAAT has also demonstrated superior sensitivity for trichomonas diagnosis in men, but it is not licensed for male specimens.^{64,72} Laboratories that have met CLIA and other regulatory requirements and validated their *T vaginalis* NAAT performance on male specimens may perform this test.^{6,34}

Disease-Specific Benefits and Risks of Screening

Benefits of routine *T vaginalis* screening have not been established. The potential benefits of screening high-risk individuals

for *T vaginalis* are to identify infections and initiate treatment of individuals and their partner(s).⁶

Clinical Considerations

Rescreening for *T vaginalis* at 3 months after treatment can be considered for females, especially HIV-infected females.⁷³ Studies that address this rescreening question for males are not in the literature.

SYPHILIS

Importance

Syphilis, nearly eliminated at the start of the new millennium, has reemerged as a public health threat, primarily among MSM. CDC data demonstrate a significant increase in syphilis among young non-Hispanic black MSM.⁸ During 2008–2012, rates for males increased most significantly among 20- to 24-year-olds. In 2006, the highest reported syphilis rates were among men aged 35 to 39 years; now rates are highest among 20- to 24-year-olds. In 2012, syphilis rates among females decreased overall compared with 2010, although rates remain highest among females aged 20 to 24 years. In 2012, the primary and secondary syphilis rate male-to-female ratio was 10.3:1.⁸ In 2012, 75% of primary and secondary syphilis cases in 49 states and the District of Columbia that provided information about gender of sex partners were among MSM.⁸

Syphilis is a treatable systemic STI caused by the spirochete *Treponema pallidum*. *T pallidum* is transmitted by exposure to the organism, most commonly through sexual contact with infected lesions, such as chancres, or in the blood of a pregnant woman through the placenta to the fetus. The most serious complications of untreated syphilis are neurosyphilis in the adult and congenital syphilis in the offspring of the pregnant female. Congenital syphilis causes a range of

multisystem problems in affected infants, including intrauterine death.²⁵

Background

The USPSTF recommends syphilis screening for individuals of both genders who at increased risk of syphilis infection, such as MSM, adults in corrections facilities, commercial sex workers, people who exchange sex for drugs, contacts of people with infectious syphilis, and pregnant females at the first prenatal visit.^{4,5} Universal syphilis screening is not recommended for nonpregnant females or heterosexual males.⁶ Providers should consult with their local health department regarding local syphilis prevalence and epidemiology, which may influence who they should screen beyond pregnant adolescents and adolescent MSM.^{6,73} The CDC recommends that a syphilis serologic screening test be performed at least annually for sexually active MSM.⁶

Laboratory Testing

Syphilis serologic tests are available to screen for syphilis. A single positive serologic syphilis test result is not diagnostic.^{6,34} A diagnosis of syphilis requires both treponemal and nontreponemal test results, along with a comprehensive clinical evaluation.^{6,34} In the United States, the traditional syphilis laboratory screening strategy is to perform a nontreponemal test, such as a rapid plasma reagin or Venereal Disease Research Laboratory test, followed by a treponemal test, such as a *T pallidum* particle agglutination (TP-PA), enzyme immunoassay, or chemiluminescent immunoassay for confirmation. Alternatively, some clinical laboratories offer the reverse sequence syphilis screening algorithm with treponemal enzyme immunoassay or chemiluminescent immunoassay and confirm active disease with quantitative nontreponemal tests.^{8,34} Additional details on this syphilis testing

algorithm are available from the Association of Public Health Laboratories.^{6,25,74}

Disease-Specific Benefits and Risks of Screening

Benefits of syphilis detection and treatment include the elimination of a potentially serious multisystem disease and prevention of cases of congenital syphilis. Syphilis screening can produce false-positive test results, which require further evaluation.

Clinical Considerations

A recent evidence-based review supports syphilis screening and treatment during pregnancy to prevent congenital syphilis.⁷⁵ People who have symptomatic syphilis might seek treatment of new onset of genital ulcers, lymphadenopathy or cutaneous or mucosal rashes, hair loss, or neurologic symptoms consistent with syphilis^{6,25} and should be tested for it. Follow-up testing is critical to confirm treatment effectiveness.⁶

CLINICAL IMPLICATIONS AND CONCLUSIONS

Female and male adolescents and young adults have high STI prevalence rates compared with other age groups. Certain adolescent populations bear a higher STI burden, such as youth of color and MSM.⁸ A comprehensive sexual history sensitive to ethnic, racial, and cultural factors, including those of sexual minority youth, and a sexual behavior risk assessment (vaginal, oral, and anal sex) should guide sites of specimen collection on the basis of sexual behavior. Clinicians should inquire about same- and opposite-gender sexual partners, regardless of reported sexual orientation. There are few available national data regarding STIs in transgender youth, although older transgender populations are at high risk of STIs, including HIV.^{76,77}

Detection of infection creates the opportunity to treat asymptomatic disease, prevent adverse sequelae, prevent further transmission to others, identify likely infected partners for testing and treatment, and reduce the burden of disease. Risks associated with screening include false-positive results, especially in low-prevalence populations, and false-negative results, which may leave diseases undetected and untreated. A positive screening result for any STI may be associated with self-blame and stigma for some individuals, which may have emotional, behavioral, and relationship repercussions.^{78–81} The presence of any STI puts an individual at greater risk of other STIs, and an evaluation for other STIs, including HIV should be considered. Pediatricians can take an active role in reducing disease prevalence and adverse sequelae by identifying and treating undiagnosed infections in addition to prevention counseling, promotion of condom use and safe sex practices, rescreening infected patients after treatment, and offering expedited partner therapy, where legally permissible and recommended,^{82,83} to prevent new and recurrent infections.⁸⁴

RECOMMENDATIONS

The American Academy of Pediatrics (AAP) recommends the following:

1. Routine laboratory screening for nonviral STIs as per the following published screening recommendations for sexually active adolescents. The following screening recommendations summarize published federal agency and medical professional organizations' clinical guidance for all sexually active adolescents:
 - a. Chlamydia
 - i. Routinely screen all sexually active female adolescents and young adults (≤ 25 years) for *C trachomatis* annually.

- ii. Routinely screen sexually active adolescent and young adult MSM for rectal and urethral chlamydia annually if they engage in receptive anal or insertive intercourse, respectively. Screen every 3 to 6 months if high risk because of multiple or anonymous partners, sex in conjunction with illicit drug use, or having sex partners who participate in these activities.
 - iii. Screen adolescents and young adults exposed to chlamydia in the past 60 days from an infected partner.
 - iv. Consider screening sexually active males annually in settings with high prevalence rates, such as jails or juvenile corrections facilities, national job training programs, STD clinics, high school clinics, and adolescent clinics for patients who have a history of multiple partners.
- b. Gonorrhea
 - i. Routinely screen all sexually active female adolescents and young adults (< 25 years) for *N gonorrhoeae* annually.
 - ii. Routinely screen sexually active adolescent and young adult MSM for pharyngeal, rectal, and urethral gonorrhea infection annually if engaging in receptive oral or anal intercourse or insertive intercourse, respectively. Screen every 3 to 6 months if high risk because of multiple or anonymous partners, sex in conjunction with illicit drug use, or having sex partners who participate in these activities.
 - iii. Screen adolescents and young adults exposed to gonorrhea

in the past 60 days from an infected partner.

- iv. Consider screening other sexually active and young adult males annually on the basis of individual and population-based risk factors, as discussed in the body of the text. For information on local prevalence rates, contact the local or state health departments. CDC gonorrhea surveillance data at state and county levels are available at www.cdc.gov/std/stats/default.htm.

c. Trichomoniasis

Routine *T vaginalis* screening of asymptomatic adolescents is not recommended. However, individual and population-based risk factors, including new or multiple partners, a history of STIs, exchanging sex for payment, or injecting drugs, may put females at higher risk of infection, and they may require a more thorough STI evaluation, including screening for *T vaginalis*.

d. Syphilis

The routine screening of nonpregnant, heterosexual adolescents is not recommended. However, screening is recommended for all sexually active adolescent and young adult MSM annually or every 3 to 6

months if high risk and can be considered for youth whose behaviors put them at higher risk. Providers should consult with their local health department regarding local syphilis prevalence and associated risks that may influence practice decisions.

2. Rescreen all adolescents infected with chlamydia or gonorrhea 3 months after treatment, regardless of whether they believe that their sex partners were treated. Providers should consider rescreening females previously diagnosed with trichomoniasis 3 months after treatment. If retesting at 3 months is not possible, retest whenever patients next present for health care services in the 12 months after initial treatment.
3. Develop clinical procedures using prepared resources to incorporate STI risk assessments, screening and treatment, and prevention counseling into routine health care for sexually active adolescents, which include the following:
 - a. Providing education and training opportunities to staff on procedures and related issues, including consent, confidentiality, and billing.
 - b. Developing competence with non-invasive NAAT screening.

4. Advocate to minimize barriers to STI screening without breaches of confidentiality and to minimize other barriers, including access and stigma.

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Standards for Pediatric Cancer Centers

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- *Policy Statement*

POLICY STATEMENT

Standards for Pediatric Cancer Centers

abstract

FREE

Since the American Academy of Pediatrics—published guidelines for pediatric cancer centers in 1986, 1997, and 2004, significant changes in the delivery of health care have prompted a review of the role of medical centers in the care of pediatric patients. The potential effect of these changes on the treatment and survival rates of children with cancer led to this revision. The intent of this statement is to delineate personnel, capabilities, and facilities that are essential to provide state-of-the-art care for children, adolescents, and young adults with cancer. This statement emphasizes the importance of board-certified pediatric hematologists/oncologists and appropriately qualified pediatric medical subspecialists and pediatric surgical specialists overseeing patient care and the need for specialized facilities as essential for the initial management and much of the follow-up for pediatric, adolescent, and young adult patients with cancer. For patients without practical access to a pediatric cancer center, care may be provided locally by a primary care physician or adult oncologist but at the direction of a pediatric oncologist. *Pediatrics* 2014;134:410–414

INTRODUCTION

A pediatric cancer center must have the staff and facilities to offer the pediatric patient with cancer treatment that are consistent with the current standard of care for his or her diagnosis. The medical staff at such a center is often composed of the primary care pediatrician, pediatric medical subspecialists, and pediatric surgical specialists such as hematologists/oncologists, surgeons, urologists, neurologists, neurosurgeons, orthopedic surgeons, radiation oncologists, pathologists, palliative care specialists, critical care physicians, emergency medicine specialists, and diagnostic radiologists. At certain institutions, hospitalists, advance practice nurses, and physician assistants may be used to provide continuous around-the-clock care. Physicians, advanced practice nurses, physician assistants, pediatric nurses, social workers, pharmacists, dietitians, child life specialists, mental health/behavioral health specialists, and other allied health professionals are among the multidisciplinary team members committed to the care of the child, adolescent, or young adult with cancer.

In the United States, the oncologic care of the child or adolescent with cancer should be directed by a pediatric hematologist/oncologist who is board certified in the subspecialty of pediatric hematology and oncology by the American Board of Pediatrics. Initial diagnostic assessment, induction therapy, and management of complications or

SECTION ON HEMATOLOGY/ONCOLOGY

KEY WORDS

cancer, pediatrics, hematology, oncology, cancer center

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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recurrences should be provided in a pediatric center that has the following personnel, facilities, and capabilities.

PERSONNEL

- Board-certified pediatric hematologists/oncologists
- Pediatric oncology nurses who are certified in chemotherapy, knowledgeable about pediatric protocols, and experienced in the management of complications of therapy; Association of Pediatric Hematology/Oncology Nurses certification is preferable
- Board-certified radiologists with specific expertise as evidenced by certification and training in the diagnostic imaging and radiologic intervention of infants, children, adolescents, and young adults
- Board-certified surgeons with expertise in pediatric general surgery
- Surgical specialists with pediatric expertise, as evidenced by certification and training in neurosurgery, urology, orthopedics, ophthalmology, otolaryngology, and gynecology
- Dentists who have completed additional training in pediatric dentistry
- A board-certified radiation oncologist trained and experienced in the treatment of infants, children, and adolescents
- Pathologists with special expertise as evidenced by certification and training in the pathology of hematologic malignancies, tumors of the central nervous system, and solid tumors in children, adolescents, and young adults
- Board-certified pediatric medical subspecialists available to participate actively in all areas of the care of the child with cancer, including anesthesiology, critical care, infectious diseases, cardiology, neurology, endocrinology and metabolism, genetics, gastroenterology, child and adolescent psychiatry, nephrology, palliative medicine, pulmonology, adolescent medicine, and behavioral and developmental specialists
- Pediatric physical and mental rehabilitation services, including pediatric physiatry and pediatric psychiatry
- Social worker(s) with experience in pediatric oncology, pediatric psychologists, child life specialists, and school reintegration specialists, and access to personnel skilled in providing family support and group services and chaplaincy personnel who provide spiritual support
- Experts with knowledge in complementary and alternative therapies
- Nutrition experts with experience in pediatrics and the capability of preparing, administering, and monitoring total parenteral nutrition
- Pharmacist(s) with experience and training in providing chemotherapy and supportive care medicines for pediatric patients with cancer; a board-certified clinical pharmacologist, where available, may be helpful in patient management
- Continued active involvement by the primary care pediatrician is important for the provision of patient- and family-centered supportive care

FACILITIES

- An immediately accessible and fully staffed, on-site PICU
- Up-to-date diagnostic imaging facilities to perform radiography, computed tomography, MRI, ultrasonography, radionuclide imaging, and angiography; positron-emission tomography scanning and other

emerging technologies are desirable

- Access to up-to-date radiation-therapy equipment with facilities for treating pediatric patients
- An established relationship with a hematopathology laboratory capable of performing cell-phenotype analysis using flow cytometry, immunohistochemistry, molecular diagnosis, cytogenetics, and polymerase chain reaction–based methodology and fluorescence in situ hybridization
- Access within the community to pediatric hemodialysis and/or hemofiltration and apheresis
- Appropriate isolation facilities for patients with severe immunosuppression, including high-efficiency particulate air (HEPA) filtration, or laminar flow rooms and positive/negative pressure rooms

CAPABILITIES

- A clinical chemistry laboratory with the capability to monitor antibiotic and antineoplastic drug concentrations
- A blood bank capable of providing a full range of products, including irradiated and leuko-depleted blood components
- A pharmacy capable of accurate, well-monitored preparation and dispensing of antineoplastic agents and investigational agents
- Access to stem cell transplant services with the capability or availability of HLA antigen typing
- Educational and training programs for health care professionals, including the primary care physician
- A regularly scheduled multidisciplinary care conference
- Care coordination of family-centered services including home health, pain management, palliative, and end-of-

life care and treatment plan compliance

- A regularly scheduled multidisciplinary pediatric tumor board
- Ability to function as the medical home incorporating anticipatory guidance as defined in Bright Futures for the child with cancer during active treatment; on completion of therapy, care may transition back to the primary care medical home with oversight by the cancer center's multidisciplinary team
- An established program designed to provide long-term, multidisciplinary follow-up of successfully treated patients at the original treatment center or by a physician-led team of health care professionals who are familiar with the potential adverse effects of treatment of childhood cancer; as survivors of childhood cancer move into adulthood, transition to an adult provider may be appropriate¹
- Membership or affiliation with a cooperative clinical trials group, such as Children's Oncology Group, to provide access to state-of-the-art clinical trials; availability of support for coordination to track patients' progress and maintain clinical trials data
- Full-time access to professional medical interpreters to ensure accurate translation and effective communication among all health care professionals and the patient and family; written materials should be available in the native language of the patient/family, and an ongoing program to deliver culturally effective care should be available
- A formal, ongoing program to continually assess and improve quality and safety including feedback from patients and families
- A formal program for cancer education for the patient, family, and/

or caregiver and instruction on self-management

- Access to instruction and learning activities for hospitalized children and adolescents

ROLE OF CENTERS IN DIAGNOSIS AND TREATMENT

More than 15 000 new cases of cancer are diagnosed in children younger than 20 years annually in the United States.^{2,3} Cancer is the second leading cause of death after accidents in children ages 5 to 14 years.

Great progress has been made in the development of successful treatment programs for children, adolescents, and young adults with cancer. These improvements have been possible because of the availability and collaboration of pediatric cancer treatment centers with collective expertise in the clinical management of children with cancer. Experienced investigators and allied health professionals recognize the importance of a national clinical trials network in developing more successful treatment strategies.⁴

The importance of comprehensive, multidisciplinary treatment in improving patient outcome in a cost-effective manner has been well documented for children with acute lymphoblastic leukemia,⁵ non-Hodgkin's lymphoma,^{6,7} brain tumors,⁸ rhabdomyosarcoma,^{6,8} Wilms tumor,⁹ and Ewing sarcoma.⁶ Almost 80% of these children can be treated successfully if modern diagnostic and therapeutic approaches are initiated expeditiously.³ Accurate diagnosis, appropriate treatment, and supportive care depend on a multidisciplinary treatment approach to children, adolescents, and young adults with cancer, an approach that is uniquely available at a pediatric cancer center. The roles of specialized nursing, pharmacy, rehabilitation, and paramedical personnel and access to increasingly complex equipment and

facilities are critical to further improving long-term survival and quality of life.

The center-based pediatric hematologist/oncologist directs the diagnostic evaluation and treatment of most children, adolescents, and young adults with cancer. Pediatric hematology/oncology is an established specialty with specific training requirements that lead to subspecialty board eligibility. Because most pediatric tumors show a striking response to specific regimens of intensive chemotherapy, pediatric hematologists/oncologists use therapies that can have substantial morbidity and potential mortality. For these therapies to be administered safely, a pediatric hematologist/oncologist who is trained and experienced in the management of children, adolescents, and young adults with cancer and who has extensive knowledge of the relevant drug indications and toxicities must oversee the care of these patients.

The pediatric hematologist/oncologist must be assisted by skilled nurses, social workers, pharmacists, nutritionists, and psychologists who specialize in pediatric oncology. Professional organizations such as the Association of Pediatric Hematology/Oncology Nurses and the Association of Pediatric Oncology Social Workers facilitate the professional growth and education of nurses and social workers. Diagnostic radiologists and radiation oncologists with specific training and interest in pediatric oncology should be available at the pediatric cancer center. Principles of surgery that are unique to childhood tumors have evolved in fields such as general (pediatric) surgery, urology, neurosurgery, and orthopedics. The presence of surgeons with demonstrated expertise in the surgical aspects of pediatric oncology has become indispensable in achieving maximum survival. A pathologist experienced in pediatric

oncology is an essential member of the multidisciplinary team at the pediatric cancer center. State-of-the-art diagnosis of many pediatric hematologic malignancies and tumors requires immunochemistry and/or molecular techniques. Because solid tumors in children, adolescents, and young adults are rare in the experience of most pathologists, an incorrect histologic diagnosis may be given when initial surgical management occurs at a non-specialized hospital. Ideally, the diagnostic biopsy should be performed at the pediatric cancer center, at which the facilities are available to order and obtain all the special studies that would be appropriate, reducing the need for repeat procedures.

PRACTICE OF PEDIATRIC ONCOLOGY OUTSIDE RECOGNIZED CENTERS

Clinical results in children with cancer have been shown to be superior when specialized diagnostic testing, supportive care, and initial cancer treatment are carried out at a pediatric cancer center.⁵⁻⁹ After diagnosis has been established and the treatment plan has been determined by the pediatric cancer center, certain aspects of care that are not investigational may be continued in the office of a primary care pediatrician for selected children when mandated by distance from the cancer center or other individual specific circumstances. In some circumstances, communication via telemedicine may be beneficial. When such a plan for shared treatment is

undertaken, it must be a collaborative effort between the pediatric cancer center and the primary pediatrician, with ongoing communication between the local and distant site. For many children, the facilities and expertise available at the pediatric cancer center are required for all aspects of therapy. However, it must be emphasized that the primary care pediatrician should retain an important supportive role for the patient with cancer and his or her family, which requires excellent regular communication between the oncologist and the pediatrician. Most of a patient with cancer's course is spent at home under the care of family members and the primary care physician. The role of families in the decision-making, care, and advocacy for the child is critical. Hematology/oncology team members must be available, responsive, and versed in discussing supportive care provided away from the tertiary center.

SUMMARY

On the basis of the effectiveness of pediatric cancer centers in treating children, adolescents, and young adults with cancer, the American Academy of Pediatrics recommends the following:

- Children, adolescents, and young adults with newly suspected and/or recurrent malignancies should be referred to a pediatric cancer center for prompt and accurate diagnosis and management. Centers that are unable to accept the referral should arrange for the child

to be seen promptly at another appropriate facility.

- Children and adolescents with newly diagnosed and/or recurrent malignancies should have their treatment coordinated by a board-certified pediatric hematologist/oncologist. Treatment should be prescribed and initiated at a pediatric cancer center, but therapy that is not investigational may be continued at a center not specialized in the care of the pediatric oncology patient. Care should be delivered with the oversight of the pediatric cancer center's multidisciplinary team.
- Multidisciplinary team members should be physician led and have pediatric expertise within their specialty area.

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Testing for Drugs of Abuse in Children and Adolescents

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- *Clinical Report*

CLINICAL REPORT

Testing for Drugs of Abuse in Children and Adolescents

abstract

FREE

Drug testing is often used as part of an assessment for substance use in children and adolescents. However, the indications for drug testing and guidance on how to use this procedure effectively are not clear. The complexity and invasiveness of the procedure and limitations to the information derived from drug testing all affect its utility. The objective of this clinical report is to provide guidance to pediatricians and other clinicians on the efficacy and efficient use of drug testing on the basis of a review of the nascent scientific literature, policy guidelines, and published clinical recommendations. *Pediatrics* 2014;133:e1798–e1807

INTRODUCTION

The recreational use of drugs is an underrecognized cause of mortality and morbidity in children and adolescents. It is, in fact, a public health priority.¹ Although annual surveys of drug use by children and adolescents may show fluctuation, the underlying rates remain high.² Numerous adverse consequences accompany use, not the least of which is the increased risk of dependence among those who began smoking, drinking, and using drugs before 18 years of age.^{3,4} Furthermore, most adults with substance use disorders initiated use during childhood or adolescence.⁵ Pediatricians are on the front lines for deterring, delaying, detecting, and diminishing the use of drugs by children. It is imperative that all pediatricians understand and are ready to use the tools and strategies effective for these endeavors.

Drug testing has been recommended in a variety of settings and clinical situations to avert substance use, to identify use as part of an assessment, or as part of treatment of individuals with substance use disorders. To date, there is little consensus among physicians regarding the indications for drug testing and little guidance on how to use this procedure effectively for any indication.⁶ The federal government has issued extensive guidance on the use of urine drug testing with federal and other employees,⁷ although this guidance is not applicable for all situations and age groups. Experts have called for further evidence-based studies to guide best practices with adolescents.⁸

The complexity and invasiveness of the procedure and limitations to the information derived from drug testing all affect its utility. The objective of this clinical report is to provide guidance on the efficacy and efficient use of drug testing on the basis of a review of the nascent scientific literature, policy guidelines, and published clinical recommendations.

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KEY WORDS

drug testing, drug testing results, positive and negative drug testing results

ABBREVIATIONS

AAP—American Academy of Pediatrics

THC—tetrahydrocannabinol

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SPECIMEN TYPES

Six biological matrices are commonly used for drug assays: urine, blood, breath, saliva, sweat, and hair. Neonates may also be tested using meconium. The choice of sample is influenced by the cost, ease of sample collection, risk of adulteration, test type (instant or laboratory based), scope of drugs being tested, time frame (acute or chronic use), time since last use, and indications for testing. Practices and laboratories should only conduct tests for which they are certified by the Clinical Laboratory Improvement Amendments.

Breath testing is mainly used by law enforcement and alcohol treatment programs for detection of recent alcohol use; it is not, however, routinely used in primary care. It is an easy-to-use, non-invasive test that is considered a good proxy for blood alcohol concentrations; urine alcohol concentrations, on the other hand, do not correlate well with blood alcohol concentrations or corresponding central nervous system impairment. Alcohol mouthwash or breath sprays used immediately before testing may result in false-positive test results.

Carbon monoxide and a nicotine metabolite known as cotinine are the 2 products in tobacco that are used for screening. Carbon monoxide can be measured in the breath up to 24 to 48 hours after smoking and then falls to nonsmoker levels. Cotinine is regarded as the best biomarker of tobacco exposure because it has a long half-life and can be measured in blood, saliva, hair, and urine.^{9,10}

Blood concentrations are most useful for detecting alcohol and other drug use that occurred within 2 to 12 hours of the test and are best correlated with the level of impairment and morbidity seen in emergency situations. Blood testing is costly because of the need for specially trained personnel and equipment and is intrusive. Because of these

drawbacks, blood testing is rarely used in the primary care setting.

Saliva (oral fluid) and sweat testing provide similar information to blood testing but are less invasive and do not require extensive training for sample collection. Saliva allows for detection of drug excreted from the blood after recent use (ie, within 24–48 hours) that may not yet be detectable in urine. It is less subject to contamination than urine; smoking and methods used to stimulate saliva production to increase specimen volume may affect the results. Therefore, this method requires patient supervision in the 30 minutes before sampling.¹¹ Point-of-care tests are available for saliva testing.¹²

Sweat may be used to detect drug use in 2 ways. First is a patch that is worn from 3 to 7 days and detects drug use that occurred just before the patch was applied (most drugs will be excreted within 48 hours) and drug use that occurs while the patch is in place. Second, a swipe may detect drug use within the past 24 hours (collection device not approved by the US Food and Drug Administration). The collection is noninvasive and has a similar cost to urine. Although difficult, environmental contamination can occur and lead to false-positive results.¹³ Specimen volume may be affected both by the patient's sweat secretion rates or removal of the patch during the collection period. The sample size obtained with oral fluid and sweat patch tests limits the ability to repeat tests and perform confirmatory testing. Both saliva and sweat assays are less standardized than urine or blood tests, and the accuracy of sweat testing remains controversial.^{14–16}

Hair testing allows for detection of past use that has occurred over an extended time because drugs and metabolites are incorporated into the hair matrix over time. Hair cannot be used for detection of use in the pre-

vious 7 to 10 days. It is most reliable for heavy, frequent past use and not for detection of recent or occasional drug use. The hair needs to be cut as close to the scalp as possible, and usually the first 3 cm is used for testing, which covers a 90-day period (hair grows 1 cm a month). If longer hair is sent, the laboratory will cut it into segments before testing, and 4 tests will allow for screening over a period of a year. If the scalp is shaved, hair from other body areas may be sent instead. However, hair grows at a slower rate on the body, and a time frame cannot be used in this circumstance. Hair collection can be directly observed and is non-invasive, hair is easily stored and transported, and adulteration and substitution is difficult. However, hair testing is not useful clinically, because it has a long window of detection. In addition, hair structure, growth rate, melanin content, hygiene, and cosmetic treatment can affect the results. Drug concentrations in hair can be altered by shampoos, bleaches, or dyes, and false-positive results may be obtained with volatile drugs such as marijuana, which may adhere to hair.^{17,18} No point-of-care tests are available; laboratory testing is costly, and it takes a long time to obtain results.

Urine testing is invasive and highly susceptible to tampering. Nonetheless, because it is well standardized and studied, less invasive than blood testing, and provides a longer window of detection for some substances, it is the most common sample used for drug testing in primary care. A physician survey⁶ found that >90% of pediatrician and family physician respondents had used urine testing with adolescent patients in their office, suggesting that the practice is quite common. In the remainder of this report, “drug testing” will refer to urine drug testing unless otherwise indicated.

URINE DRUG TESTS

Two types of drug testing assays are available: qualitative tests usually used for screening and quantitative tests used for confirmation. Qualitative tests are point-of-care tests and home drug test kits. They are easy to perform, relatively inexpensive, and use immunoassays, such as enzyme-linked immunoassay or radioimmunoassay, that give instant positive or negative results. Although they are sensitive and function well as screening tests, they are susceptible to cross-reactions, resulting in false-positive results, which limit their specificity. Some laboratories use qualitative tests as a "screening procedure"; in this method, negative test results are discarded, and only positive test results are run through more expensive confirmatory testing, although the 2-step procedure has become less common as the cost of confirmatory testing has decreased. Confirmatory tests are performed in laboratories and not at the point of care. Most laboratories use a combination of gas chromatography and mass spectrometry and can positively identify a substance and generate quantitative concentrations.

INDICATIONS FOR DRUG TESTING

The illicit and often secretive nature of substance use may result in adolescents being unwilling to give accurate information about their substance use, and thus drug testing may yield important information, as in the various situations discussed below.

Emergent Clinical Care

Drug testing may identify possible toxins when a patient presents with altered mental status. In truly emergent situations, consent may be inferred, and testing should be considered in accident victims, after a suicide attempt, for unexplained

seizures, for syncope or arrhythmias, or in the presence of toxidromal signs and symptoms that render the patient incapable of informed consent. In the case of a toxidrome, physical findings should guide the clinician to test for a specific panel of substances, even with minimal or no history available. A positive test result for a substance suspected on the basis of clinical findings is less likely to be a false-positive or spurious result because of the higher pretest probability in this setting. However, drug testing has significant limitations, even in the emergency setting. Standard laboratory tests detect drug metabolites with an unreliable frequency and often have reference ranges far lower than therapeutic dosages; thus, they may identify substances that are present but not causing the observed symptoms. Emergency management of an obtunded patient, such as the decision to give naloxone, is made on clinical grounds and not on the basis of results of a laboratory test. Nonetheless, the results of a drug test may be helpful in determining management once the patient is stabilized.¹⁹

Assessment of Behavioral or Mental Health Symptoms

Drug use by teenagers often presents to medical attention with nonspecific signs and symptoms (such as fatigue, excessive moodiness, school failure) and, as such, may be hard to diagnose definitively. Voluntary drug testing may be a useful part of an assessment when a parent, clinician, or other adult suspects recent or ongoing drug use on the basis of observed symptoms. Like any other laboratory procedure, drug testing should be an adjunct to a thorough history rather than a replacement. In cases in which an adolescent denies use, a positive drug test result may afford an opportunity to begin an honest conversation. Drug testing may be unnecessary if a patient

is forthcoming regarding his or her drug use history. Unfortunately, significant limitations to laboratory drug testing limit the information garnered from the procedure (see "Sources of Error in Interpreting Urine Drug Tests"). Like any other laboratory test, drug test results must always be interpreted within the context of history, including both collateral and self-reports when possible.

THERAPY AND MONITORING

Drug testing programs that use contingency management strategies may be an effective therapeutic adjuvant for patients with substance use problems or disorders.^{20,21} Patients typically receive either positive reinforcement, such as cash rewards or small gifts, when a drug test result is negative or negative consequences when a drug test result indicates ongoing drug use.²² Research has consistently demonstrated the efficacy of these programs among adults, and emerging research suggests that drug testing is acceptable and effective with adolescents and young adults participating in drug abuse treatment programs.²³ Drug testing is also frequently used as a deterrent for juveniles in the probation system. Juvenile drug courts, which include frequent drug testing, have been shown to decrease substance use more so than traditional family courts. It has been suggested that even in the absence of additional therapies, the monitoring function of testing can be an effective discouragement from use.^{24,25} The effective drug testing programs that have been described in the literature are relatively expensive, are staff intensive, and may not be well suited for primary care. Engaging parents and supporting them in implementing appropriate contingencies could decrease the overall expenses of such

a program; when appropriate, parental monitoring may also serve as a contingency, with negative results intrinsically rewarding. One study found that a drug-testing program in which parents received test results from the physician would be acceptable to adolescents,²⁶ although to date, no study has demonstrated the effectiveness of such an approach.

SCREENING

A national survey of physicians found that few respondents use “suspicionless” drug testing as a means of screening for drug use in the medical home,⁶ and most experts agree that drug tests are not a useful screening procedure for general clinical populations because their sensitivity for detecting drug use in unselected populations is low.^{27,28} However, home-, school-, or employment-based programs may include a screening component (ie, unselected or general populations may be tested) to detect or deter drug use. Participant consent should be required for all of these programs, as it would be in a clinical setting.

Results of studies of school-based drug testing programs are mixed: drug testing has poor sensitivity for detecting drug use, although some studies have found a deterrent effect. The American Academy of Pediatrics (AAP) does not endorse widespread implementation of school-based drug testing because of the limited efficacy, its cost, and the potential for unintended effects, such as breach of confidentiality. School-based drug testing is discussed in greater detail in a separate AAP statement.²⁹

HOME DRUG TESTING

Drug tests have been commercially available and marketed to parents to prevent adolescent drug use for the

past 15 years. Marketing Web sites often include “home drug testing policies” that recommend drug testing on either a routine basis to prevent drug use or when a parent has specific concerns.³⁰ Home drug testing has been endorsed by several school districts and police departments around the country. To date, the efficacy of home drug testing for reducing substance use by adolescents has not been rigorously tested. The AAP does not endorse home drug testing because of concerns about the complexity of testing with significant potential for parents to misinterpret test results, limited evidence that home drug testing reduces drug use, and theoretical concerns about a negative effect on the relationship between parents and their children. A professional evaluation should be considered whenever a parent has concerns about substance use.³¹

SCHOOL CLEARANCE

Some schools require “medical clearance,” including a negative drug test result, before readmitting a student who has been suspended for drug use or possession. In these cases, the AAP suggests that the pediatrician conduct a thorough history to understand the student’s level of drug involvement. Although there are no specific guidelines for “medical clearance,” the AAP suggests that students who have been caught with drugs or paraphernalia or who were impaired at school should be allowed to return to school (after disciplinary consequences set by the school). At the conclusion of a medical evaluation, it is important to include a plan for follow-up and/or treatment in addition to considering a return to school, unless assessment suggests a serious substance use disorder requiring a more restrictive treatment setting, in which case the adolescent should be referred. The AAP cautions that “clearance” has no

uniformly accepted definition in the medical or legal literature; various individuals, such as parents, teachers, and school administrators may have different interpretations of clearance than do pediatricians. Pediatricians could, therefore, report the following as appropriate: (1) the student has received an appropriate medical evaluation and (2) reasonable medical standards indicate that return to school is a reasonable option. Furthermore, parents must consider their adolescent’s individual risks and benefits while continuing to monitor their adolescent’s behaviors.

A drug test may be particularly useful for adolescents who report limited or infrequent drug use. In these cases, a negative test result would be expected and would support the adolescent’s history. A brief period of monitoring with random tests may further support the student’s history of limited use. Adolescents who report heavy use, particularly of marijuana, are likely to have a positive drug test result even several days to weeks after termination of use. In these cases, a period of monitoring until a negative test result is obtained may be useful, although the AAP suggests that the adolescent return to school while awaiting a negative test result. Quantitative tetrahydrocannabinol (THC) concentrations may be followed to distinguish between prolonged excretion and ongoing drug use. These levels should be corrected for urine concentration to improve accuracy; one common method is to calculate a THC-to-urine creatinine ratio.³²

A student or parent may refuse a drug test and instead accept the school’s consequences or fight them. There is little legal precedent with regard to whether a school has the right to insist on a drug test from an individual student in this situation; however, 2 Supreme Court decisions both supported

a school's right to require drug testing for students who participate in sports or other extracurricular activities.^{33,34} The AAP suggests that the pediatrician advise the student and family in this situation to submit to a drug test and then advocate for returning to school as outlined previously, although ultimately, the student and his or her parent determine how to proceed.

SOURCES OF ERROR IN INTERPRETING URINE DRUG TESTS

False-Positive Results

Like any medical laboratory test, drug testing can yield false-positive or false-negative results. In urine drug testing, a "clinical" false-positive result (ie, drug detection in the absence of illicit drug use) is more likely to occur on a screening test because of cross-reactivity with an unrelated substance in the urine. For example, fluoroquinolone antibiotics have been reported to cross-react with immunoassay opiate screens.^{35,36} Confirmatory tests are highly unlikely to yield false-positive results but can yield a "clinical false-positive" result when a patient takes a certain prescription medication or ingests a food that metabolizes into a substance included in the drug testing panel. For example, a patient taking amphetamine and dextroamphetamine for attention-deficit/hyperactivity disorder will have a positive test result for amphetamines, which may be falsely positive for substance abuse. Unfortunately, drug testing cannot distinguish between appropriate use and misuse of prescribed medications. To interpret drug test results accurately, it is necessary to know an individual's complete medical history, including prescribed medications. In addition, the practitioner needs to know the limitations of the selected matrix, the substances for which the drug panel tests, and potential cross-reactivity. The practitioner should not

hesitate to ask for assistance in ordering the correct test or interpreting results.

False-Negative Results

A negative drug test result does not necessarily mean that an adolescent is not using a particular substance. The urine specimen submitted may not be a valid sample, as when an adolescent attempts to evade a positive test by submitting someone else's urine, dilutes his or her own urine, or adds an adulterating (or "masking") agent to the sample to interfere with the screening immunoassay (eg, soap, bleach, ammonia). Even in the absence of adulteration, use may escape detection because of the timing of use relative to the testing, or if the cutoff concentration for a positive test result is set too high, small amounts of drug or metabolite may be missed. Another example occurs when the psychoactive substance used is not part of the standard test panel, resulting in a "clinical false-negative" test result (eg, "spice" and newer designer drugs). Test panels often use a common metabolite to identify an entire class of substances (see Table 1). However, individual substances with variant metabolism can still be missed. For example, benzodiazepine panels that identify oxazepam will not identify clonazepam, which is commonly misused by adolescents but not metabolized through this pathway. Thus, interpreting drug test results can be exquisitely complex, even for experienced clinicians, and should be done with caution. Seeking assistance from the testing laboratory is important, particularly when test results do not correlate with clinical findings and when a physician suspects the use of a particular substance that is not included in a test panel.

URINE SPECIMEN COLLECTION

An accurate test result is dependent on obtaining a proper specimen. Direct observation is the most reliable

method for specimen collection. It is recommended that each treatment facility have a protocol in place that describes how urine specimens intended for drug testing will be collected from both male and female patients. It is also recommended that random specimens or those taken without supervision be labeled as such. Specimens that may have pertinence to a legal matter (eg, those taken after a motor vehicle crash or as part of a court-ordered program) may require collection in a tamper-proof container and also require chain of custody. When this is not practical, the patient should be referred to a laboratory facility that has this capability.

A less-invasive collection method involves excluding coats and bags and using a specially prepared restroom without running water, soap, or other chemicals. Toilet water should be tinted. The specimen's appearance and color should be documented and the temperature should be taken within 4 minutes, preferably by use of a collection container with a temperature-sensitive strip on the outside. The temperature should be recorded within 4 minutes of collection and should range from 90°F to 100°F (32°–38°C). The procedure should be explained to the patient before any collection. A national survey of physician practices found that most offices use none of these procedures (although many provide a staff member outside the door to listen for running water).³⁷ If unsupervised collection is used, results should be interpreted with caution.

Modesty

In all cases, the need to obtain information from a drug test must be balanced with protecting an adolescent's dignity. If a reasonable balance cannot be attained, the pediatrician might consider forgoing a drug test and basing

TABLE 1 Approximate Duration of Detectability and Common Cutoffs for Selected Drugs

Drug	Metabolite	Window of Detection	Comments
Alcohol	Alcohol	7–12 h	Ethyl succinate and ethyl glucuronide can persist in the urine up to 5 d after heavy alcohol use. However, use of hand sanitizer, mouthwash, cough syrup, etc, can result in low levels without “alcohol use.”
	Ethyl succinate, ethyl glucuronide	Up to 5 d	
Amphetamines			Note that methylphenidate is not detected on a routine amphetamine panel; therefore, a positive amphetamine test result cannot be explained by use of a methylphenidate preparation.
Amphetamine (AMP)	MAMP	1–3 d	
Methamphetamine (MAMP)	>100 ng/mL of AMP+MAMP	1–2 d	
3,4-MethylenedioxyAMP	MDA	1–2 d	
3,4-MethylenedioxyMAMP	MDMA	1–2 d	
Barbiturates			
Pento/secobarbital	Secobarbital	Short-acting, 4–6 d	
Butalbital	Secobarbital	Intermediate, 3–8 d	
Phenobarbital	Secobarbital	Long-acting, 10–30 d	
Benzodiazepines			Most benzodiazepine screens identify oxazepam and will not pick up all benzodiazepines. If evaluating a patient for benzodiazepine use, it is important to find the specific drug on the test panel or speak with the laboratory personnel.
Triazolam	Hydroxyethyl flurazepam	Short-acting, 1 d	
Clonazepam	7-amino Clonazepam	Intermediate, 1–12.5 d	
Diazepam	Oxazepam	Long-acting, 5–8 d	
Chronic use		Can last 30 d after last use	
Cocaine	Benzoylcegonine	1–3 d	Note that synthetic cannabinoids will not be picked up on a cannabinoid screen. If use of synthetic cannabinoids is suspected, speak to the laboratory regarding availability of tests for these substances.
Cannabinoids	Carboxy-THC	Single use, 1–3 d	
		Moderate use, 4 d; heavy use, 10 d	
		Chronic, 3–5 wk after last use	
		4 h	
Lysergic acid diethylamide (LSD)	Nor-LSD		
Methadone	Methadone and metabolite 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	1 d–1 wk	
Opiates			
Morphine (M)	Morphine	1–2 d	
Codeine (C)	Morphine and codeine	1–2 d	
Semisynthetic opiates	Hydrocodone	1–2 d	
	Hydromorphone	1–2 d	
	Oxycodone	1–3 d	
	Oxymorphone	1.5–2.5 d	
Heroin	6-acetyl-morphine +morphine	<24 h up to 1–2 d	6-acetyl-morphine is pathognomonic for heroin use but has a narrow time window and is most often not detected on a drug test. A test that is positive for morphine outside of the use of prescribed morphine is suggestive of heroin use.
Phencyclidine (PCP)	Phencyclidine	Casual use, 2–10 d Chronic use, several weeks	

clinical decisions on history and physical examination alone. This may include referring a patient for further evaluation or treatment on the basis of a high index of suspicion of drug use. Signs and symptoms of a mental health, behavioral, or substance use disorder

should not be discounted because of inability to obtain a drug test.

CONFIDENTIALITY

Many national organizations, including the AAP, have consistently cautioned

against involuntary drug testing in adolescents.³¹ Adolescents should be engaged in their own care and, in most states, can consent to substance abuse treatment on their own.^{38,39} Drug testing of a competent adolescent without his or her consent is, at best, impractical

and without his or her knowledge is unethical and illegal. However, an adolescent's refusal to consent to a drug test should not prematurely conclude an evaluation of a substance use problem or disorder. If a pediatrician suspects that an adolescent is using drugs and that adolescent is refusing a drug test, his or her refusal should be documented, and referral to an addiction or mental health specialist is warranted. Pediatricians may also coach parents on appropriate limit setting or discipline. For example, a parent may suspend driving privileges if there is suspicion that an adolescent is using psychoactive substances; privileges may be restored if the teenager can reasonably demonstrate that he or she is not using substances.

Adults who have a long-term relationship with an adolescent are often aware of early behavioral, mental health, and physical changes that may prompt the request for drug testing. Before drug testing, the pediatrician should get a detailed description of the concerns to formulate a differential diagnosis and determine whether a drug test may be a helpful part of an assessment. If so, a discussion about the limited scope of information available from testing as well as the need to reach a consensus on an action plan for both positive and negative results should be undertaken. This will make any intervention easier to implement. The concerns raised by the adult and the recommendation for a drug test should then be discussed with the adolescent, and assent, including permission to share results, should be obtained before testing. If an adolescent refuses to consent to sharing the drug test results with a parent then they should not be shared. If the drug test was requested by the parents, the pediatrician should explain to them that their son or daughter has not consented to release

drug test results. However, as in all situations, if an adolescent's behavior puts him or her at acute risk of harm to self or others, the pediatrician should consider breaching confidentiality.

MANAGEMENT

Ideally, drug test results may reassure parents or lead to an honest conversation about drug use that can guide further intervention. Unfortunately, if managed poorly, drug test results may be contentious, cause friction between an adolescent and his or her parents, and create a difficult situation for the clinician to manage. The AAP believes good outcomes are more likely if the pediatrician reviews how test results will be managed *before* a test is sent to the laboratory.

In most instances in which a drug test is ordered for an adolescent patient, parents will want to know the results, and with few exceptions, sharing drug test results with parents is a helpful part of the process of drug testing. One exception would be a treatment-seeking adolescent who does not want to inform parents, and testing is used as a form of therapy. This situation is rare in primary care, but if encountered, the pediatrician should respect the engaged adolescent's autonomy. Adolescents younger than 18 years are able to consent to substance use treatment without parental consent in more than half of the United States. It is important for the practitioner to learn about laws governing confidentiality in the states in which they practice.

Positive Test Results

Because drug tests may yield false-positive test results, we suggest that the clinician always review positive results first with the adolescent to determine whether something other than substance misuse may explain the observed results. The

pediatrician should consider both the laboratory results and the history before assessing the likelihood of substance use and presenting information back to parents.

The pediatrician may begin the interaction by informing the adolescent that the drug test gave unexpected results (which could refer to a test interpreted by the physician as positive, dilute, or adulterated) and asking for more information. In some instances, the adolescent may report substances not detected on the panel, ultimately yielding more information than the test results alone conveyed. If the adolescent's report matches the drug test results, the pediatrician can begin a conversation about the next steps, which may include an abstinence trial, ongoing testing, and/or a referral to counseling or other treatment. If reports of drug use match the results of a point-of-care test, confirmatory testing, which adds considerable expense, could reasonably be omitted.

If an adolescent denies substance use despite a positive drug test result without a reasonable alternative explanation, the pediatrician can present available information to parents (assuming consent has been obtained). Laboratory testing is not perfect, and spurious results are possible. Repeat drug testing may be of value; adolescents with serious drug disorders are likely to ultimately have multiple positive drug test results.

Negative Test Results

A negative drug test result can support a history of no recent drug use and may be reassuring to parents and pediatrician. However, the pediatrician should not dismiss ongoing behavioral or mental health symptoms just because a drug test result is negative. Rather, a referral for a more in-depth mental

health evaluation is warranted in such cases.

A single negative drug test result does not exclude the possibility of drug use or a substance use disorder. If a substance use disorder is highly suspected on a clinical basis, the pediatrician should consider the possibility of a substituted, adulterated, or diluted sample; use of a substance not detected by the test panel; or a missed window of detection. If one of these conditions is suspected, other testing considerations include repeating the urine test serially, using a different matrix, changing the method (eg, to laboratory testing if a point-of-care test was used), adding specimen validity testing, or changing/adding to the test panel. In addition, the pediatrician should consider referral to an addiction or mental health specialist for further evaluation. Paradoxically, a “falsely” negative drug test result (ie, a test result that is negative despite ongoing drug use) might inadvertently delay detection and treatment of a substance use disorder if symptoms are dismissed and further evaluation is not pursued.

Dilute Specimens

All urine drug test orders should include a check for specimen integrity. Creatinine, which is a product of muscle metabolism, is used as a marker of urine concentration and should be ordered with each sample. Urine samples with a random creatinine concentration between 2 and 20 mg/mL should be considered dilute. Some of these samples may be positive for one or more 1 substances and should be considered both positive *and* dilute because it is possible to miss substances present in lower concentrations (eg, a urine specimen may test positive for marijuana

but be too dilute to identify low levels of cocaine).

Dilute specimens present a difficult clinical challenge in interpreting drug test results. Smaller adolescents or those with less muscle mass are more likely to have lower random urine creatinine concentrations. Adolescents may consume a large volume of fluid before the test either spuriously to be able to produce a urine specimen rapidly, or intentionally to attempt to defeat the test. These different scenarios cannot be distinguished on the basis of drug test results alone, and clinical correlation is warranted. In these cases, a repeat drug test may also be helpful. First-morning specimens generally result in samples with adequate concentration. If a first-morning specimen is not possible, the adolescent can limit fluid intake in the few hours before providing a specimen.

Substituted or Adulterated Specimens

Urine specimens that have been substituted or adulterated in vitro should always be considered “positive” and may represent a serious substance use disorder and/or co-occurring mental health or behavioral disorder. In these cases, referral to an addiction specialist or mental health expert is warranted. Substituted specimens may be cold, may have a urine creatinine concentration ≤ 2 mg/mL, or may be found in the adolescent’s possessions. Adulterated specimens may have an unusual color or smell, may have out-of-range pH, or may result in a positive “adulterant panel” (available from some commercial laboratories). In these cases, if drug testing is to be repeated, observed urine collection may reduce the opportunity to tamper with the specimen.

Managing Confidentiality Between Patients and Outside Entities

Care should be taken to protect all information about substance use, including historical reports and drug test results that are recorded in the medical record. In primary care, the Health Insurance Protection and Accountability Act of 1996 (Pub L No. 104-191) stipulates how all medical records must be protected and can only be released via signed informed consent or other legally authorized means. For care provided in a substance abuse treatment program, federal substance abuse confidentiality regulations (CFR 42 Part 2) supersede the Act and provide even more stringent criteria for release of information (the form must designate the specific information to be released).

Before releasing any information to any outside entity, the AAP recommends that the clinician consider potential advantages and risks of doing so. Pediatricians often have an opportunity to play the role of an intermediary between schools, probation officers, or other organizations and their adolescent patients, and having information pass through the pediatrician can offer a number of advantages. For example, the pediatrician can interview the adolescent and parent to help interpret drug test results before releasing information from the laboratory. In the case of a true positive result indicating recent drug use, the pediatrician can discuss a plan for monitoring and/or treatment that can be provided along with the drug test results. The recipient of the information will likely appreciate expert advice on level of care, and this type of input may help to prevent consequences such as school expulsion or custody for probation violations and instead direct adolescents into appropriate care for substance use disorders. Ultimately, however, patients, in conjunction with parents, decide to whom drug testing and other information may be released.

SUMMARY

Drug testing is a complex procedure that, when used properly, may have a number of clinical indications. However, drug testing also has a number of drawbacks; it can be invasive, it yields only limited information, and results are easily misinterpreted. Drug testing should never be the sole basis for making a diagnosis of a substance use disorder; rather, test results should be used to supplement information obtained by history and physical examination. Signs and symptoms of

a mental health, behavioral, or substance use disorder should not be dismissed solely on the basis of a negative drug test result or inability to obtain a test; these symptoms always require further evaluation, and referral to a specialist should be considered.

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Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

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- *Policy Statement*

- *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



POLICY STATEMENT

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

KEY WORDS

RSV, respiratory syncytial virus, palivizumab, bronchiolitis, infants and young children, chronic lung disease, congenital heart disease

ABBREVIATIONS

AAP—American Academy of Pediatrics
CHD—congenital heart disease
CLD—chronic lung disease
COID—Committee on Infectious Diseases
RSV—respiratory syncytial virus

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The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

(Continued on last page)

abstract

FREE

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 *Red Book. Pediatrics* 2014;134:415–420

Policy statements from the American Academy of Pediatrics (AAP) are designed to provide updated guidance for child health care topics, with an emphasis on evidence-based recommendations whenever possible. Policy statements are reviewed at least every 3 years and updated when appropriate. In following this procedure, the AAP Committee on Infectious Diseases (COID) has undertaken a systematic review of all recent and older peer-reviewed literature relating to the burden of respiratory syncytial virus (RSV) disease in infants and children, focusing on publications that delineate children at greatest risk of serious RSV disease and studies that define pharmacokinetics, safety, and efficacy. Detailed input regarding this guidance has been solicited from 21 committees, councils, sections, and advisory groups within the AAP, as well as organizations outside the AAP. Outside groups include the American College of Chest Physicians, American College of Emergency Physicians, American Thoracic Society, Emergency Nurses Association, National Association of Neonatal Nurses, National Association of Neonatal Nurse Practitioners, and Society of Hospital

Medicine. In addition, this review includes all data presented to the COID by the manufacturer of palivizumab.

As part of this deliberative review of palivizumab use, the COID judged the quality of the available data, as well as the impact of palivizumab prophylaxis to reach a unanimous consensus on guidance for the use of palivizumab in the United States. Cost was considered during deliberations by the COID and Bronchiolitis Guideline Committee, but the final guidance as presented here is driven by the limited clinical benefit derived from palivizumab prophylaxis.^{1–3}

As detailed in the accompanying technical report,⁴ the benefit resulting from this drug is limited. Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing.

This policy statement updates and replaces the most recent AAP recommendations for the use of palivizumab prophylaxis published in 2012 in the 29th edition of the *Red Book*.⁵ This policy statement offers specific guidance for the use of palivizumab on the basis of available evidence, as well as expert opinion. A detailed discussion of the foundation of the updated guidance for each category as well as the references for each section may be found in the accompanying technical report,⁴ and AAP guidelines for the diagnosis and management of bronchiolitis, which were published in 2006⁶ (for which a revision is forthcoming).

The palivizumab package insert states: “Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.”⁷ In the absence of a specific definition of “high risk” by the US Food and Drug Administration, the AAP has endeavored to provide pediatricians and other health care providers with more

precise guidance for determining who is at increased risk since palivizumab was first licensed.^{5,8–11}

The informed opinion of the COID and the Bronchiolitis Guidelines Committee, as well as others participating in the current statement, is that palivizumab use should be restricted to the populations detailed below.

PRETERM INFANTS WITHOUT CHRONIC LUNG DISEASE OF PREMATURITY OR CONGENITAL HEART DISEASE

Palivizumab prophylaxis may be administered to infants born before 29 weeks, 0 days’ gestation who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

Available data for infants born at 29 weeks, 0 days’ gestation or later do not identify a clear gestational age cutoff for which the benefits of prophylaxis are clear. For this reason, infants born at 29 weeks, 0 days’ gestation or later are not universally recommended to receive palivizumab prophylaxis. Infants 29 weeks, 0 days’ gestation or later may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.

Palivizumab prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.

Some experts believe that on the basis of the data quantifying a small increase in risk of hospitalization, even for infants born earlier than 29 weeks, 0 days’ gestation, palivizumab prophylaxis is not justified.

PRETERM INFANTS WITH CLD

Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop

CLD of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth.

During the second year of life, consideration of palivizumab prophylaxis is recommended only for infants who satisfy this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life prophylaxis is not recommended.

INFANTS WITH HEMODYNAMICALLY SIGNIFICANT CHD

Certain children who are 12 months or younger with hemodynamically significant CHD may benefit from palivizumab prophylaxis. Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.

Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist.

These recommendations apply to qualifying infants in the first year of life who are born within 12 months of onset of the RSV season.

The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal

defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)

- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15 mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

Children younger than 2 years who undergo cardiac transplantation during the RSV season may be considered for palivizumab prophylaxis.

CHILDREN WITH ANATOMIC PULMONARY ABNORMALITIES OR NEUROMUSCULAR DISORDER

No prospective studies or population-based data are available to define the risk of RSV hospitalization in children with pulmonary abnormalities or neuromuscular disease. Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection and, therefore, may be considered for prophylaxis during the first year of life.

IMMUNOCOMPROMISED CHILDREN

No population based data are available on the incidence of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation. Severe and even fatal disease attributable to RSV is recognized in children receiving chemotherapy or who are immunocompromised because of other conditions, but the efficacy of prophylaxis in this cohort is not known. Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

CHILDREN WITH DOWN SYNDROME

Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome. However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.

CHILDREN WITH CYSTIC FIBROSIS

Routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is not recommended unless other indications are present. An infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis. Continued use of palivizumab prophylaxis in the second year may be considered for infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

RECOMMENDATIONS FOR TIMING OF PROPHYLAXIS FOR ALASKA NATIVE AND AMERICAN INDIAN INFANTS

On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.

Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

DISCONTINUATION OF PALIVIZUMAB PROPHYLAXIS AMONG CHILDREN WHO EXPERIENCE BREAKTHROUGH RSV HOSPITALIZATION

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

USE OF PALIVIZUMAB IN THE SECOND YEAR OF LIFE

Hospitalization rates attributable to RSV decrease during the second RSV season for all children. A second season of palivizumab prophylaxis is recommended only for preterm infants born at <32 weeks, 0 days' gestation who required at least 28 days of oxygen after birth and who continue to require

supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season.

LACK OF THERAPEUTIC EFFICACY OF PALIVIZUMAB

Passive antibody administration is not effective in treatment of RSV disease and is not approved or recommended for this indication.

PREVENTION OF HEALTH CARE-ASSOCIATED RSV DISEASE

No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose. Infants in a neonatal unit who qualify for prophylaxis because of CLD, prematurity, or CHD may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge.

Strict adherence to infection-control practices is the basis for reducing health care-associated RSV disease.

RSV SEASONALITY

Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. If

prophylaxis is initiated in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

Variation in the onset and offset of the RSV season in different regions of Florida may affect the timing of palivizumab administration. Data from the Florida Department of Health may be used to determine the appropriate timing for administration of the first dose of palivizumab for qualifying infants. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida.

Sporadic RSV infections occur throughout the year in most geographic locations. During times of low RSV prevalence (regardless of proportion of positive results), prophylaxis with palivizumab provides the least benefit because of the large number of children who must receive prophylaxis to prevent 1 RSV hospitalization.

EFFECT OF PALIVIZUMAB PROPHYLAXIS ON SUBSEQUENT WHEEZING

Prophylaxis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.

SUMMARY OF GUIDANCE

- In the first year of life, palivizumab prophylaxis is recommended for infants born before 29 weeks, 0 days' gestation.
- Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation.
- In the first year of life, palivizumab prophylaxis is recommended for preterm infants with CLD of prematurity, defined as birth at <32 weeks, 0 days'

gestation and a requirement for >21% oxygen for at least 28 days after birth.

- Clinicians may administer palivizumab prophylaxis in the first year of life to certain infants with hemodynamically significant heart disease.
- Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.
- Palivizumab prophylaxis is not recommended in the second year of life except for children who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy).
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
- Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
- Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.
- Insufficient data are available to recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome.
- The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native

populations and possibly in selected other American Indian populations.

- Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease.

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(Continued from first page)

ERRATA**RSV Policy Statement —Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014;134(2):415–420**

An error occurred in the policy statement from the American Academy of Pediatrics titled “Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection” published in the August 2014 issue of *Pediatrics* (2014;134[2]:415–420). On pages 417–418, the last sentence in the section titled **Use of Palivizumab in the Second Year of Life** should read: “A second season of palivizumab prophylaxis is recommended only for preterm infants born at <32 weeks, 0 days’ gestation who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, chronic systemic corticosteroid therapy, or *diuretic* therapy within 6 months of the start of the second RSV season.” Bronchodilator therapy has been removed as a consideration for prophylaxis in the second RSV season.

We regret this error.

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Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

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- *Technical Report*

- *PPI: AAP Partnership for Policy Implementation*
See Appendix 2 for more information.



TECHNICAL REPORT

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

abstract

FREE

Guidance from the American Academy of Pediatrics (AAP) for the use of palivizumab prophylaxis against respiratory syncytial virus (RSV) was first published in a policy statement in 1998. Guidance initially was based on the result from a single randomized, placebo-controlled clinical trial conducted in 1996–1997 describing an overall reduction in RSV hospitalization rate from 10.6% among placebo recipients to 4.8% among children who received prophylaxis. The results of a second randomized, placebo-controlled trial of children with hemodynamically significant heart disease were published in 2003 and revealed a reduction in RSV hospitalization rate from 9.7% in control subjects to 5.3% among prophylaxis recipients. Because no additional controlled trials regarding efficacy were published, AAP guidance has been updated periodically to reflect the most recent literature regarding children at greatest risk of severe disease. Since the last update in 2012, new data have become available regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effects of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, and the effect of prophylaxis on wheezing and palivizumab-resistant RSV isolates. These data enable further refinement of AAP guidance to most clearly focus on those children at greatest risk. *Pediatrics* 2014;134:e620–e638

Palivizumab is a humanized mouse immunoglobulin (IgG1) monoclonal antibody produced by recombinant DNA technology. The antibody is directed against a conserved epitope of the A antigenic site of the fusion (F) protein of respiratory syncytial virus (RSV) and demonstrates both neutralizing and fusion inhibitory activity.¹ The antibody consists of 2 heavy chains and 2 light chains; 95% of the amino acid sequences (framework) are of human origin, and 5% (antigen binding sites) are of mouse origin. After intramuscular administration, palivizumab is distributed hematogenously throughout the body, including the lower respiratory tract. When RSV encounters palivizumab in the lower respiratory tract, antibody binds to F protein and prevents the structural

COMMITTEE ON INFECTIOUS DISEASES and BRONCHIOLITIS GUIDELINES COMMITTEE

KEY WORDS

RSV, respiratory syncytial virus, palivizumab, bronchiolitis, infants and young children, chronic lung disease, congenital heart disease

ABBREVIATIONS

AAP—American Academy of Pediatrics
 CDC—Centers for Disease Control and Prevention
 CHD—congenital heart disease
 CI—confidence interval
 CLD—chronic lung disease
 COID—Committee on Infectious Diseases
 FDA—US Food and Drug Administration
 HSCT—hematopoietic stem cell transplant
 KID—Kids' Inpatient Database
 NVSN—New Vaccine Surveillance Network
 PHIS—Pediatric Health Information System
 QALY—quality-adjusted life year
 RSV—respiratory syncytial virus
 SOT—solid organ transplant

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conformational change that is necessary for fusion of the viral RSV envelope with the plasma membrane of the respiratory epithelial cell.² Without fusion, the virus is unable to enter the cell and unable to replicate. In addition, palivizumab prevents cell-to-cell fusion of RSV-infected cells.²

BACKGROUND

Palivizumab was licensed by the US Food and Drug Administration (FDA) in June 1998, largely on the basis of results of the IMpact-RSV trial conducted during the 1996–1997 RSV season. This randomized, placebo-controlled, double-blind trial involved 1501 infants and young children born preterm (at or before 35 weeks' gestation), some of whom had chronic lung disease (CLD) of prematurity.³ The IMpact-RSV trial demonstrated an RSV hospitalization rate of 10.6% in the placebo arm and 4.8% among high-risk infants who received prophylaxis, a reduction of 5.8% in RSV hospitalizations ($P < .001$).³ A second randomized, double-blind, placebo-controlled trial conducted from 1998 to 2002 enrolled 1287 children with hemodynamically significant congenital heart disease (CHD).⁴ This cardiac trial evaluated both the safety and efficacy of palivizumab prophylaxis and demonstrated an RSV hospitalization rate of 9.7% in the placebo arm and 5.3% among recipients of palivizumab prophylaxis, a reduction in the RSV hospitalization rate of 4.4% ($P < .003$). No additional placebo-controlled trials regarding the efficacy of palivizumab prophylaxis in any other subgroup have been published.

Palivizumab was licensed for the prevention of severe lower respiratory tract disease in pediatric patients at increased risk of severe RSV disease.¹ Recommendations from the American Academy of Pediatrics (AAP) for use of prophylaxis have evolved since licensure

of palivizumab as additional information has become available.

In addition, peer-reviewed data have been published since preparation of the most recent guidance in 2012.⁵ This technical report reviews the newer and older scientific literature to offer guidance on the most appropriate use of palivizumab prophylaxis, as published in the accompanying policy statement.⁶ Current guidance is risk stratified, targeting infants at greatest risk of severe disease and most likely to benefit from prophylaxis on the basis of evaluation of the published literature. Therefore, not all infants enrolled in the 2 randomized trials are included in the current guidance. Twenty-one AAP sections and committees plus groups outside the AAP have contributed to and concur with the updated guidance presented in the accompanying policy statement.

AAP guidance regarding the use of palivizumab was first published in a policy statement⁷ in 1998 and subsequently was revised in a 2003 policy statement,⁸ the 2006 *Red Book*,⁹ a 2009 policy statement,¹⁰ and most recently in the 2012 *Red Book*.⁵ The AAP guidance for palivizumab prophylaxis is being updated at this time to reflect the ongoing assessment by the Committee on Infectious Diseases (CID) of peer-reviewed publications, as exemplified in the following areas:

- Data regarding palivizumab pharmacokinetics¹¹;
- Data on the seasonality of RSV circulation^{12,13};
- Data on overall declining incidence of hospitalizations for bronchiolitis in the United States¹⁴;
- Data demonstrating that mortality rates in children hospitalized with laboratory-confirmed RSV are lower than previously estimated¹⁵;
- Data demonstrating a statistically significant but clinically minimal

reduction of wheezing episodes among recipients of palivizumab prophylaxis^{16,17};

- Reports indicating little benefit of palivizumab prophylaxis among patients with cystic fibrosis or Down syndrome^{18–20};
- Reports describing palivizumab resistant RSV isolates from hospitalized patients who receive prophylaxis^{21–23}; and
- Independently conducted cost analyses demonstrating a high cost versus limited benefit from palivizumab prophylaxis.^{24,25}

In addition, the complexity of the current guidance has resulted in lack of prophylaxis for some children who qualify, whereas other children who do not qualify receive prophylaxis that may not be indicated.^{26,27} The goal of this updated guidance is to present more clearly the CID recommendations for palivizumab use for infants and young children who are most likely to derive benefit from prophylaxis and, in the process, to simplify guidance for pediatricians and other clinicians. It is important to note that using the same aggregate data, prophylaxis guidelines from other countries such as the United Kingdom are more restrictive than AAP guidance for the United States, and no evidence of excess morbidity has been observed.^{28,29}

Indications contained in a package label reflect data from clinical trials conducted by the sponsor and submitted to the FDA for drug licensure. The FDA does not issue guidelines or recommendations for drug use. The palivizumab package inserts states “Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.”¹ In the absence of a specific definition of “high risk” by the FDA, the AAP has endeavored since palivizumab was

first licensed to provide more precise guidance for determining those at increased risk.^{5,7,8,10} The same is true with this revision.

ADMINISTRATION

Palivizumab is administered intramuscularly at a dosage of 15 mg/kg once a month. The drug is packaged in single-dose liquid solution vials at 50 mg/0.5 mL and 100 mg/1.0 mL and does not contain preservative. A vial cannot be stored once it is opened, so a vial-sharing scheme is important to minimize waste. Anaphylaxis has occurred after palivizumab administration after initial exposure or reexposure, with some cases of severe hypersensitivity reactions reported.¹

RSV IMMUNOPROPHYLAXIS AND VACCINE ADMINISTRATION

Palivizumab does not interfere with the immune response to live or inactivated vaccines. The childhood immunization schedule should be followed for all children, regardless of palivizumab use.¹

GUIDANCE FOR PALIVIZUMAB PROPHYLAXIS

Burden of RSV Disease

In the United States, RSV remains an important cause of hospitalization in the first months of life. Retrospective analyses using national databases and *International Classification of Diseases, Ninth Revision* discharge diagnoses have shown considerable variation in estimates of annual hospitalization rates attributable to RSV for infants.^{30–33} More recent prospective population-based studies of laboratory confirmed cases demonstrate that RSV hospitalization rates are approximately half the rates reported in retrospective studies, yet rates remain high.^{14,34–36}

It is estimated that approximately 2.1 million children younger than 5 years

require medical care as inpatients or as outpatients for RSV infection annually. Among outpatients, 60% (1.3 million) are 2 through 5 years of age, and the remaining 40% are between birth and 2 years of age.³⁵ Approximately 25% of RSV-infected children younger than 5 years are assessed and treated in an emergency department, and approximately 70% are assessed and treated in a pediatric office. It is estimated that each year, nearly 58 000 children in the first few years of life are hospitalized because of RSV infection.³⁵ Infants in the second month after birth have the highest RSV hospitalization rate, a rate that is almost twice that of the next highest risk group (infants in the first month after birth).³⁴

Preterm Infants Without CLD

In 2012, 3.95 million births were reported in the United States. Preterm infants (singleton and multiple births) born at less than 37 weeks' gestation represented 11.6% of all births.³⁷ Preterm births of infants at less than 28 weeks' gestation accounted for 0.7% of the annual birth cohort.³⁷ Infants born from 32 weeks to 35 weeks' gestation represented approximately 9% of the birth cohort.

Beginning with the first AAP statement in 1998,⁷ the high cost of palivizumab influenced recommendations for use by the COID, leading to attempts to identify risk factors for RSV hospitalization among the large number of moderately preterm infants. The New Vaccine Surveillance Network (NVSN), sponsored by the Centers for Disease Control and Prevention (CDC) was a prospective population-based surveillance program from 3 geographically diverse locations in the United States for young children hospitalized with laboratory-confirmed RSV respiratory illness. Several studies were published summarizing data from the NVSN. One

conducted during the RSV seasons from 2000 through 2005 using multiple logistic-regression analyses of data revealed that some of the previously reported potential risk factors, including siblings in the household and child care attendance, were not associated with a significantly increased risk of RSV hospitalization.³⁴ In this study, only young chronologic age was significantly correlated with risk of hospitalization for RSV illness. The association between preterm birth and increased risk of severe illness was not specific for RSV.³⁵

In addition, data from the NVSN study revealed that for all preterm infants (<37 weeks' gestation), the RSV hospitalization rate was 4.6/1000 children, which was not significantly different from the hospitalization rate for term infants, which was 5.3/1000 children (Table 1).³⁴ Rates were derived from 132 085 children born during the study period, among whom 2149 were hospitalized with acute respiratory illness, and 559 of the hospitalized children had laboratory-confirmed RSV (Table 1). Infants born at <30 weeks' gestation experienced a higher RSV hospitalization rate (18.7/1000 children) than early preterm infants (30–33 weeks),³⁴ although the small number of infants born before 30 weeks' gestation limits the generalizability of this data. Late preterm infants were hospitalized significantly less often than term infants for RSV infection.³⁴

An analysis of Tennessee Medicaid data for children younger than 3 years conducted from July 1989 to June 1993 (preimmunoprophylaxis era) included 248 652 child-years of follow-up. The retrospective cohort analysis was conducted to determine RSV hospitalization rates among infants with different degrees of prematurity and other comorbidities.³⁸ Within each age group, preterm infants had similar

TABLE 1 Average RSV Hospitalization Rates Among Children Younger Than 24 Months (2000–2005)³⁴

Children <24 mo	N ^a	RSV Hospitalization Rate/1000	95% CI
All infants regardless of gestational age	559 ^b	5.2	4.8–5.7
All term infants (≥37 wk gestation)	479	5.3	4.9–5.8
All preterm infants (<37 wk gestation)	56	4.6	3.4–5.8
≥35 wk gestation	494	5.1	4.7–5.5
32–34 wk gestation	23	6.9	4.3–10.1
29–31 wk gestation	6	6.3	2.0–12.4
<29 wk gestation	12	19.3	8.4–34.0
All very preterm (<30 wk gestation)	15 ^c	18.7	10.0–30.0

^a Among 2149 enrolled hospitalized children from a birth cohort of 132 085 children.

^b The total of 559 children hospitalized with RSV includes 24 whose gestational age could not be verified.

^c Personal communication, Geoffrey A. Weinberg, MD.

rates of RSV hospitalization, regardless of the degree of prematurity (Table 2). In this analysis, preterm infants with CLD were categorized separately to reduce confounding.

A historical cohort analysis from Rochester, New York, reported on RSV hospitalization rates among 1029 consecutive preterm infants born before or at 32 weeks' gestation during a 5-year period.³⁹ The RSV hospitalization rate increased with decreasing gestational age, with a breakpoint at ≤28 weeks' gestation (Table 3). Among infants born at or before 26 weeks' gestation, the risk of RSV-associated hospitalization was 13.9% vs 4.4% among children hospitalized at >30 to 32 weeks' gestation. There was not a statistically significant difference in RSV hospitalization rates between infants with gestational ages of >28 to 30 weeks and infants with gestational ages of >30 to 32 weeks.

A retrospective cohort study of infants enrolled in Medicaid in Texas and

Florida between 1999 and 2004 examined RSV hospitalization rates in moderately preterm infants 32 to 34 weeks' gestation.⁴⁰ Less than 20% of each cohort received palivizumab prophylaxis. In Florida, 71 (3.1%) of the moderately preterm infants were hospitalized compared with 1246 (1.5%) of term infants, and in Texas 164 (4.5%) of the preterm infants were hospitalized compared with 3815 (2.5%) of term infants. Palivizumab prophylaxis was associated with decreased hospitalization in moderately preterm infants in Texas but not in Florida. The risk of RSV hospitalization in moderately preterm infants was similar to 1-month-old term infants by 4.2 months in Florida (95% confidence interval [CI], 2.5–5.7) and by 4.5 months in Texas (95% CI, 2.8–6.4).⁴⁰

Choosing an appropriate cutoff for gestational age for which palivizumab prophylaxis may be considered for preterm infants without other indications is challenging. Data consistently

demonstrate the greatest increase in risk for hospitalization is in preterm infants born before 29 weeks' gestation. These infants have hospitalization rates 2 to 4 times higher than later preterm infants (Tables 1, 2, and 3). The consensus of the COLD and the Bronchiolitis Guidelines Committee is that palivizumab prophylaxis may be considered for infants, without other indications, whose gestational age is less than 29 weeks (28 weeks, 6 days or fewer). The available data do not support universal recommendations for palivizumab prophylaxis for preterm infants born at or after 29 weeks' gestation.

Data regarding the risk of RSV hospitalization for most preterm infants do not support a benefit from prophylaxis. In recent large cohort studies of moderately preterm infants, the majority of whom did not receive palivizumab, 2.5% to 4.9% required hospitalization for RSV infection during the RSV season indicating that more than 95% did not require hospitalization.⁴⁰ The rate of hospitalization among infants ≥35 weeks' gestation (5.1/1000) was no different than the rate for term infants (5.3/1000; Table 1). The hospitalization rate of infants ≥30 weeks to 35 weeks' gestation indicate only a slight increase in risk (less than twofold; Tables 1, 2, and 3). Data concerning host or environmental risk factors for hospitalization in preterm infants without CLD or CHD are inconsistent, with the exception of age

TABLE 2 RSV Hospitalizations per 1000 Children From >248 000 Child-Years of Follow-up³⁸

Age Stratum/Risk Group	0 to <6 mo	6 to <12 mo	12 to <24 mo	IRR (95% CI) for 0 to <6 mo	Adjusted IRR (95% CI) for first 12 mo
Low-risk infants	44.1	15.0	3.7	Comparator	Comparator
Infants with CHD	120.8	63.5	18.2	2.7 (2.2–3.4)	2.8 (2.3–3.3)
Infants with CLD	562.5	214.3	73.4	12.8 (9.3–17.2)	10.7 (8.4–13.6)
≤28 wk gestation	93.8	46.1	30.0	2.1 (1.4–3.1)	2.4 (1.8–3.3)
29 to <33 wk gestation	81.8	50.0	8.4	1.9 (1.4–2.4)	2.2 (1.8–2.7)
33 to <36 wk gestation	79.8	34.5	10.8	1.8 (1.5–2.1)	1.8 (1.6–2.1)
Other condition ^a	122.3	55.2	24.1	2.8 (2.5–3.1)	2.3 (2.1–2.6)

IRR, incidence rate ratio.

^a Asthma, cystic fibrosis, cancer, HIV infection, immunodeficiency, steroid therapy, chronic renal disease, diabetes mellitus, congenital anomalies of the respiratory tract, or respiratory distress syndrome.

TABLE 3 RSV Hospitalizations Among 1029 Infants Born at or Before 32 Weeks' Gestation³⁹

Gestational Age, wk	No. of Infants	No. of RSV Admissions	% Admitted	<i>P</i> vs 30–32 Weeks' Gestation
≤26	165	23	13.9	<.001
27–28	171	17	9.9	.007
>28–30	240	18	7.5	.12
>30–32	453	20	4.4	Comparator
Total	1029	78	7.6	Not applicable

younger than 3 months at the start of the RSV season, which has been associated with an increased risk of hospitalization.³⁴

For all infants, particularly those who are preterm, the environment should be optimized to prevent RSV and other viral respiratory infections by offering breast milk feeds, immunizing household contacts with influenza vaccine, practicing hand and cough hygiene, and by avoiding tobacco or other smoke exposure and attendance in large group child care during the first winter season, whenever possible.

Preterm Infants With CLD

Studies have documented that infants and young children with CLD have increased rates of RSV hospitalization.^{38,39} Results from the IMpact-RSV trial evaluating all preterm infants with CLD (*n* = 762 randomized preterm infants) demonstrated that the RSV hospitalization rate among placebo recipients was 12.8% and 7.9% among palivizumab recipients (*P* = .038).³

Infants With Hemodynamically Significant CHD

The results of an industry-funded multicenter, randomized, double-blind, placebo-controlled trial of palivizumab prophylaxis among 1287 children (639 palivizumab recipients, 648 placebo recipients) younger than 24 months with hemodynamically significant CHD was published in 2003.⁴ Results from this study demonstrated a reduction in RSV hospitalization rates of 4.4% (9.7% among placebo recipients and 5.3% among palivizumab recipients;

P = .003).⁴ The reduction in the number of RSV hospitalizations between the 2 study groups was 29 fewer RSV hospitalizations among palivizumab recipients during the 4 years of the study.⁴ Prophylaxis with palivizumab appeared to have less benefit among cyanotic children than among acyanotic children. Among children in the cyanotic group, there were 23 fewer RSV hospitalizations per 1000 palivizumab recipients (7.9% vs 5.6%, *P* = .285). Among children in the acyanotic group, there were 68 fewer RSV hospitalizations per 1000 prophylaxis recipients (11.8% vs 5.0%; *P* = .003). Despite enrolling 1287 subjects, the trial did not have sufficient power to detect statistically significant differences among subgroups of children with different cardiac lesions.

A retrospective analysis of the effect of palivizumab prophylaxis on RSV hospitalizations among children with hemodynamically significant CHD was conducted in California. The authors estimated a statewide 19% reduction in RSV hospitalization between 2000 and 2002 (preprophylaxis era) and 2004 and 2006 (prophylaxis era) after the licensure of palivizumab for children with CHD. The authors concluded that in the state of California, 7 fewer RSV hospitalizations per year occurred among children younger than 2 years with hemodynamically significant CHD following recommendations for palivizumab prophylaxis in this group.⁴¹

Other investigators describe rates of RSV hospitalizations among patients with hemodynamically significant CHD (2%–3%) who do not receive pro-

phylaxis as lower than the 9.7% rate reported in the placebo arm of the cardiac study.^{42–46} As the rate of RSV hospitalization decreases among children who do not receive prophylaxis, the cost to prevent 1 hospitalization with prophylaxis increases.

A retrospective analysis of children younger than 3 years (248 652 child-years) in the Tennessee Medicaid program revealed that the RSV hospitalization rate for children with CHD in the second year of life (18.2/1000) was less than half the hospitalization rate for low-risk infants in the first 5 months after birth (44.1/1000), a group for whom palivizumab prophylaxis is not recommended³⁸ (Table 2). Thus, prophylaxis is not recommended during the second year of life.

Children With Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

The risk of RSV hospitalization is not well defined in children with neuromuscular disorders that impair the ability to clear secretions from the upper airway because of ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy.

Studies suggest children and infants with neuromuscular disease who are hospitalized with RSV infection tend to be older compared with other groups of patients hospitalized with RSV infection and are more likely to have preexisting immunity to RSV.^{47,48} This may reflect the progressive nature of neuromuscular disease, with susceptibility to respiratory disease tract increasing with age.

Immunocompromised Children

Population-based data are not available on the incidence or severity of RSV disease among children who receive

solid organ transplants (SOTs) or hematopoietic stem cell transplants (HSCTs), children who receive chemotherapy, or children who are immunocompromised because of other conditions. Progression of RSV infection from upper to lower respiratory tract disease depends on the virulence of the RSV strain, as well as specific abnormalities in the immunocompromised host's immune response attributable to the underlying disease or to chemotherapy.

RSV infection in immunocompromised children and adults can progress to respiratory failure and death.^{49,50} Lymphopenia has been recognized as a risk factor for disease progression in several studies of immunocompromised patients. One study in adults noted that progression of RSV to lower respiratory tract disease did not occur in patients with a lymphocyte count greater than 1000 cells/mm³ at time of onset of upper respiratory tract infection.⁵¹ An absolute lymphocyte count of 100 cells/mm³ or less at the time of RSV upper tract infection was associated with progression to lower respiratory tract disease. In contrast to lymphopenia, analysis of antibody concentration in these adult HSCT recipients indicated no correlation between preexisting anti-RSV antibody concentration and progression from upper to lower respiratory tract disease.⁵¹

A retrospective report from 1 institution described 58 immunocompromised children with RSV infection between 1997 and 2005.⁵² Sixty-five percent of the RSV-infected children were managed as outpatients. No deaths occurred among 28 children infected with RSV who were receiving chemotherapy for acute lymphoblastic leukemia or among 11 immunosuppressed SOT recipients. Five of 58 patients with lower respiratory tract infection died (8.6%), including 4 children who were allogeneic HSCT recipients and

1 child with severe combined immune deficiency. One of the deaths occurred in a 10-year-old child, and a second death occurred in a child with *Aspergillus* species coinfection. Profound lymphopenia (<100 cells/mm³) was associated with progression to lower respiratory tract disease.⁵²

Another retrospective report from 1 institution noted 5 deaths among 117 RSV-infected, immunocompromised patients between 2006 and 2011 (2 with severe combined immunodeficiency, 1 with uncharacterized immunodeficiency, 1 with chronic granulomatous disease, and 1 SOT recipient).⁵³ The deaths occurred in children who presented with community-acquired RSV lower respiratory tract infection. No deaths occurred among children who were HSCT recipients or those with leukemia or lymphoma.

A third retrospective review of RSV infections in children with cancer was conducted from 1998 to 2009.⁵⁴ Among 57 patients, 37% experienced progression to lower respiratory tract disease. Three patients died of respiratory failure within 60 days of RSV diagnosis (1 had concomitant bacteremia and fungemia and 1 had concomitant herpes simplex pneumonia).

In a review of 208 viral respiratory infections among 166 patients over a 13-year period who received HSCTs, SOTs, or chemotherapy for malignancy, RSV infection accounted for 43% of the infections.⁵⁵ The mean and median ages of patients at the time of infection were 6.1 years and 4.3 years, with a range of 2 months to 21 years of age. Death occurred in 17 (8%) of patients with viral respiratory infection, including 6 of 88 (7%) RSV-infected children who received allogeneic HSCTs or SOTs. No infection resulted in death among patients who received chemotherapy, despite being severely immunosuppressed. Mortality and morbidity

did not have a statistically significant correlation with the degree of immune suppression.

Risk factors for a poor outcome after RSV infection in an immunosuppressed host include age younger than 2 years, presence of lower respiratory tract symptoms at presentation (particularly in the absence of symptoms of upper respiratory infection), corticosteroid therapy, and varying degrees of lymphopenia. Underlying diagnosis, degree of immune suppression, RSV load in bronchoalveolar lavage, or specific humoral immunity to RSV have not been found to correlate with outcome.⁵⁶ This inability to correlate degree of immunosuppression with disease severity indicates an incomplete understanding of the immune response to viral respiratory infections in an immunocompromised host.

Antibody-based treatments, including immune globulin and palivizumab, have not been associated with improved outcome in HSCT recipients.⁵⁷ No data are available to suggest benefit from immunoprophylaxis among immunocompromised patients, and practices vary nationwide.^{58,59} Further research is required before definitive recommendations can be made for the use of palivizumab in this heterogeneous group of children.

Children With Down Syndrome

Several factors appear to place children with Down syndrome at increased risk of RSV lower respiratory tract disease than children without Down syndrome.^{18,19,60,61} CHD, with or without pulmonary hypertension, occurs in approximately 45% of children with Down syndrome, and lesions include atrioventricular canal, ventricular septal defect, patent ductus arteriosus, and tetralogy of Fallot. Anatomic abnormalities of the upper or lower respiratory tract, muscle dystonia, and intrinsic immune dysfunction may

contribute to viral respiratory disease in this population.

One population-based cohort study over an 11-year period in Colorado revealed a statewide total of 85 RSV hospitalizations among 680 children with Down syndrome during their first 2 years of life. Concurrent risk factors were present in 35 of the 85 (41%) hospitalized children, indicating they would have qualified for prophylaxis for other reasons. RSV hospitalization rates were 67/1000 child-years for children with Down syndrome and other risk factors, 42/1000 child-years for children with Down syndrome without cardiopulmonary disease, and 12/1000 child-years for children in a control group.⁶¹ These data suggest an estimated overall 7.7 RSV admissions per year (85 admissions per 11 years) in the state of Colorado for children with Down syndrome. Using these figures, 4.6 RSV hospitalizations per year occur among children with Down syndrome without concurrent factors (50 admissions per 11 years) in Colorado. Assuming a 55% reduction in hospitalization, approximately 2 to 3 hospitalizations per year might have been avoided from prophylaxis administered to 680 children. Although children with Down syndrome were more likely to experience a temperature >38°C, the median duration of stay for children younger than 1 year of age with Down syndrome was 4 days, and for children without Down syndrome the median was 3 days. No deaths were reported in this study.⁶¹ These data suggest children with Down syndrome have a slightly higher hospitalization rate, but the absolute number of RSV hospitalizations is small, and a number of children with Down syndrome are at increased risk because of qualifying heart disease or other factors.

Another report described 39 of 395 (9.9%) children with Down syndrome hospitalized because of RSV infection

in the first 2 years of life.⁶⁰ Among hospitalized children, 38% had hemodynamically significant heart disease. This study had insufficient power to differentiate among subgroups, meaning the increased RSV hospitalization rate may have been explained by concurrent risk factors and not Down syndrome.⁶⁰ Another study of 41 children with Down syndrome hospitalized with RSV infection noted that 51% had underlying CHD.¹⁸ An additional report of 222 children with Down syndrome hospitalized with RSV infection noted the mean age of hospitalized children (1.3 years; range, 0–6.1 years) was significantly older than the age of children hospitalized with RSV who did not have Down syndrome. A similar finding was noted in the Colorado report, with a mean age of 9.6 months at admission for RSV infected patients with Down syndrome and no other risk factors. In this study, the age range for hospitalization extended through 17 years.⁶¹ RSV prophylaxis for the first year of life would have limited effect on RSV hospitalization for children with Down syndrome without other risk factors for RSV.^{19,61}

Children With Cystic Fibrosis

Available studies indicate the incidence of RSV hospitalization in children with cystic fibrosis is uncommon and unlikely to be different from children without cystic fibrosis. Evidence to support a benefit from palivizumab prophylaxis in patients with cystic fibrosis is not available.^{20,62,63}

A randomized clinical trial with palivizumab prophylaxis included 186 children with cystic fibrosis from 40 centers. One subject in the untreated group and 1 subject in the palivizumab group were hospitalized for RSV infection.⁶⁴ Although this study was not powered for efficacy, no clinically meaningful differences in outcome between the 2 groups were reported.

At the 12-month follow-up, there was no significant difference between the treated and untreated groups in number of *Pseudomonas* colonizations or change in weight-to height ratio. A case-control study of palivizumab in 75 children with cystic fibrosis noted a possible trend toward a potential clinical benefit of palivizumab prophylaxis, but the difference was not statistically significant.⁶²

A large study of RSV hospitalizations occurring between 1997 and 2003 in Danish children with chronic medical conditions identified 72 children with cystic fibrosis.⁶⁵ There were 13 RSV-related hospitalizations, which resulted in an adjusted incidence rate ratio for risk of RSV hospitalization of 4.32 (95% CI, 2.42–7.71). The geometric mean ratio for duration of RSV hospitalization in these children with cystic fibrosis was 1.3 days (95% CI, 0.81–2.11 days).

Two recent reviews^{20,66} of RSV infection in infants with cystic fibrosis acknowledged that infants with cystic fibrosis may have a slightly increased risk for hospitalization with RSV. However, they both stated that there is insufficient evidence related to safety and efficacy in infants with cystic fibrosis to support a recommendation of palivizumab prophylaxis.^{20,66} A survey of cystic fibrosis center directors published in 2008 noted that palivizumab prophylaxis is not the standard of care for patients with cystic fibrosis.⁶⁷

Discontinuation of Palivizumab Prophylaxis Among Children Who Experience Breakthrough RSV Hospitalization

RSV is classified into subgroups A and B, based on antigenic differences in the surface G glycoprotein. Subgroups are classified further into genotypes based on genetic analysis. The ability of RSV to cause reinfections throughout life likely

is attributable both to strain variability and to an immune response that does not fully protect against subsequent infection. Reinfections with both heterologous and homologous strains occur. More than 1 RSV strain may circulate concurrently in a community. However, repeat RSV hospitalizations during 1 season are rare.

One study identified 726 RSV lower respiratory tract infections among 1560 children younger than 5 years over 8 successive RSV seasons in an outpatient setting.⁶⁸ Only 1 instance of repeat RSV infection occurred during the same season. Furthermore, it is well established that repeat RSV infections are associated with less severe clinical illness than the initial RSV infection.^{69,70}

In the blinded and randomized cardiac trial that involved 1287 children younger than 24 months with hemodynamically significant CHD, a total of 5 readmissions for a second RSV hospitalization occurred (a rate of less than 0.5%). Three of 648 children in the placebo group and 2 of 639 children who received palivizumab had more than 1 RSV hospitalization over 4 years.⁴

In the Dutch trial of 429 preterm infants randomly assigned to receive either palivizumab prophylaxis or placebo between April 2008 and December 2010, infants were followed for recurrent wheezing. No RSV reinfections were detected in either group, again indicating that repeat RSV infections in the same year seldom occur.¹⁶

Use of Palivizumab in the Second Year of Life

A prospective population-based surveillance study of 5067 children younger than 5 years evaluated 564 children hospitalized with laboratory-confirmed RSV infection. Among the children hospitalized with RSV infection, 75% were younger than 12 months. Less than 20% of all pediatric RSV hospitalizations

occurred during the second year of life.³⁵

Limited safety data and no efficacy data are available regarding palivizumab prophylaxis in the second year of life.^{71,72} Regardless of the presence or absence of comorbidities, RSV hospitalization rates decline during the second RSV season for all children.^{34,38} In a retrospective cohort study conducted over 4 years and involving 248 652 child-years, RSV hospitalization rates in the second year of life for children with comorbidities were lower than the rate for healthy term infants in the first 12 months of life, a group for whom prophylaxis is not recommended³⁸ (Table 2).

Lack of Therapeutic Efficacy of Palivizumab

Controlled studies have demonstrated that monoclonal antibodies have no therapeutic benefit in the treatment of RSV infected children. One randomized study determined that intravenous palivizumab administered to RSV-infected, intubated infants reduced the RSV viral load in the lower respiratory tract but had no effect on RSV concentration in the upper respiratory tract.⁷³ Despite a reduction in viral load in the lower respiratory tract, no difference in disease severity was found between palivizumab recipients and placebo recipients. A phase 2 therapeutic trial involving 118 hospitalized, RSV infected infants evaluated the outcome among recipients of intravenous motavizumab at 30 mg/kg or at 100 mg/kg compared with placebo.⁷⁴ Motavizumab is an investigational monoclonal antibody with enhanced potency relative to palivizumab. No significant effect on RSV viral load in the upper respiratory tract was detected among motavizumab recipients. No difference in duration of hospitalization, requirement for supplemental oxygen, ICU admission, or need for mechanical ventilation between groups was detected.

Prevention of Health Care-Associated RSV Disease

Strict infection-control practices, including restriction of visitors to the neonatal ICU during respiratory virus season, will decrease health care-associated RSV disease. Evidence does not support the use of palivizumab among hospitalized preterm infants to prevent health care-associated spread of RSV.^{75,76} If an RSV outbreak occurs in a high-risk unit (eg, pediatric or neonatal ICU or HSCT unit), primary emphasis should be placed on proper infection-control practices, especially hand hygiene. No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease. Further, hospitalization rates for RSV infection do not differ among infants who receive inpatient palivizumab prophylaxis while in the neonatal ICU compared with those who initiate prophylaxis at hospital discharge.⁷⁷

CONSIDERATIONS AFFECTING REVISION OF GUIDANCE

Risk Factors for RSV Hospitalization

Overall, approximately 2% to 3% of infants in the first 12 months of life are hospitalized with RSV infection each year in the United States. Children with certain comorbidities are at increased risk of severe RSV disease relative to children without these comorbidities.^{35,38} Chronologic age is the single most important risk factor for RSV hospitalization on the basis of the observation that more than 58% to 64% of pediatric RSV hospitalizations occur in the first 5 months after birth.^{34,35,38} Most of these hospitalizations occur in the first 90 days after birth.^{22,34,40} Certain subgroups of infants with comorbidities such as prematurity, CLD, or hemodynamically significant CHD have increased risks for RSV hospitalization, although the

degree of risk varies among studies.^{30,78} The risk of RSV hospitalization associated with most other risk factors has been difficult to determine because of low rates of occurrence. Most host and environmental factors increase the risk for RSV hospitalization by only a small magnitude, so their contribution to overall disease burden is limited.⁷⁹ In addition, these factors are not identified consistently from study to study. These inconsistencies likely reflect variation in practice patterns in different countries, variation in living conditions and climate, variation in health care coverage, yearly variation in disease severity, and incompletely understood genetic factors. Differences in study design may contribute to these differences.

Reported host risk factors of limited (inconsistent) impact include the following: congenital malformations, congenital airway anomaly, neuromuscular impairment, birth weight, gender, lack of breastfeeding, duration of breastfeeding, cord serum anti-RSV antibody concentration, small for gestational age, Down syndrome, epilepsy, cord blood vitamin D concentration, family history of atopy, viral load, malnutrition, multiple births, and singletons versus multiple birth subjects. Environmental risk factors of limited (variable) impact include the following: environmental pollution, crowded living conditions, living at increased altitude, meteorological conditions, low parental education, low socioeconomic status, child care attendance, size of child care facility, month of birth, smoke exposure, maternal smoking during pregnancy, and proximity to hospital care.^{30,35,38,47,48,60,65,78,80–94} One publication suggested that malformations of the urinary tract increase the risk of RSV hospitalization.⁶⁵

Multiple logistic-regression analyses of data from the 4-year population-based prospective study revealed that

of the evaluated risk factors (male gender, child care attendance, smoke exposure, lack of breastfeeding, and other children in the house), only preterm birth and young chronologic age independently correlated with more severe RSV disease after adjusting for other covariates.³⁵

RSV Seasonality

During the 6 RSV seasons from July 2007 to January 2013, the median duration of the RSV season ranged from 13 to 23 weeks, with median peak activity from mid-December to early February, with the exception of Florida and Alaska (see later discussions for each).^{12,13} Within the 10 Health and Human Services Regions, in the few regions when the RSV season began in October, the season ended in March or early April. In regions where the RSV season began in November or December, the season ended by April or early May. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months of serum palivizumab concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States.¹¹ Children who qualify for 5 monthly doses of palivizumab prophylaxis should receive the first dose at the time of onset of the RSV season. For qualifying infants born during the RSV season, fewer than 5 doses will be needed to provide protection until the RSV season ends in their region (maximum of 5 doses).

A small number of sporadic RSV hospitalizations occur before or after the main season in many areas of the United States,^{79,95} but maximum benefit from prophylaxis is derived during the peak of the season and not when the incidence of RSV hospitalization is low.

Prophylaxis for Alaska Native/American Indian Children and Timing of Palivizumab Initiation

Hospitalization rates for all causes of bronchiolitis as high as 484 to 590/1000 infants have been described in isolated Inuit populations.^{96–99} Alaska Native infants in southwestern Alaska experience higher RSV hospitalization rates and a longer RSV season. On the basis of the epidemiology of RSV in Alaska, particularly in remote regions, the selection of infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for appropriate timing of palivizumab administration.¹⁰⁰

Two published studies have documented a bronchiolitis hospitalization rate in Navajo populations that was 91.3 to 96.3/1000 infants younger than 1 year.^{101,102} This rate was similar to those seen with high-risk groups, such as infants born preterm and those with CLD. There are no data on efficacy of palivizumab in this population. However, if local data support a high burden of RSV disease in select American Indian populations, selection of infants eligible for prophylaxis may differ from the remainder of the United States for infants in the first year of life.

Timing of Prophylaxis for the State of Florida

Variation in the onset and offset of the RSV season in different regions of Florida may affect the timing of palivizumab administration. Florida Department of Health data may be used to determine the appropriate timing for administration of the first dose of palivizumab for qualifying infants. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly

doses of palivizumab will be adequate for qualifying infants for most RSV seasons in Florida. Even if the first of 5 monthly doses is administered in July, protective serum concentrations of palivizumab will be present for most infants and young children for at least 6 months and likely into February. More than 5 monthly doses are not recommended, despite the detection of a small number of cases of RSV infection outside this time window. A small number of sporadic RSV hospitalizations occur before or after the main season in many areas of the United States, but maximum benefit from prophylaxis is derived during the peak of the season and not when the incidence of RSV hospitalization is low.

Pharmacokinetics of Palivizumab

A threshold protective serum palivizumab concentration in humans has not been established. On the basis of studies of palivizumab prophylaxis with the cotton rat, serum concentrations of 25 to 30 mcg/mL produced a mean reduction in pulmonary RSV concentrations of 99% ($2 \log_{10}$).^{103,104} Because of the reliability of the cotton rat model to predict results in humans, this serum concentration became the target trough concentration in the randomized clinical trials.^{3,4} The package label states “palivizumab serum concentrations of greater than or equal to 40 mcg/mL have been shown to reduce pulmonary RSV replication in the cotton rat model of RSV infection by 100 fold.”¹

Palivizumab pharmacokinetic data published by the manufacturer in 2012 demonstrate that after 5 monthly doses, serum concentrations of palivizumab remain at or above protective levels for most children for at least 6 months (>24 weeks).¹¹ There is seldom justification to administer more than 5 doses within the continental United States. These data were derived from

a computer model based on 22 clinical trials.

Weight dosing at 15 mg/kg resulted in similar palivizumab concentrations in healthy term infants as well as pre-term infants.¹¹

Race and Sex

Data from the NVSN demonstrate that the overall rate of RSV hospitalization does not differ between African American and white children younger than 24 months of age (5.4/1000 for African American children and 4.7/1000 for white children).³⁴ Among infants younger than 6 months, RSV hospitalization rates for African American and white children were not significantly different.³⁴ Another report from NVSN evaluated 564 children hospitalized with RSV infection. Neither race nor ethnic group was found to be an independent risk factor for hospitalization.³⁵ A third CDC report revealed rates of RSV coded illness in African American and white children to be similar at 5.3/1000 (95% CI, 3.7–6.9/1000) and 5.3/1000 (95% CI, 4.3–6.3/1000), respectively.³³ Hospitalization rates did not differ during the years of this study (1997–1999 and 2004–2006) by African American or white race. In this study, hospitalization rates for RSV-coded illness were 7.5/1000 boys (95% CI, 5.9–9.1) and 5.9/1000 girls (95% CI, 4.5–7.3).

Another population-based study evaluated racial disparities between African American and white children who were hospitalized because of RSV infection in 3 large United States counties.¹⁰⁵ No disparity was found in any county for any of the 7 years studied among children in the first 12 months of life or between infants 0 to 2 months or infants 3 to 5 months of age. Because of small numbers, reliable estimates for other race groups are not available.³³ RSV hospitalization

rates among boys exceed that of girls in some, but not all studies.^{34,35}

Mortality Rates Among Hospitalized Children With RSV Infection

Using 2 national databases (the Pediatric Health Information System [PHIS] data for 2004–2011 and the Health Cost and Utilization Project Kids' Inpatient Database [KID] for 2009), mortality rates associated with hospitalized infants with RSV infection were lower than previously estimated. The PHIS data set from 44 children's hospitals identified 33 deaths per year (13.7 deaths/10 000 RSV admissions during the RSV season), but only 8.5 deaths/10 000 admissions were coded with RSV as the primary diagnosis, suggesting that other comorbidities were involved. In the KID data set from more than 4000 hospitals in 44 states, RSV was estimated to account for 121 deaths annually in the United States (9/10 000 RSV admissions) with 84 deaths per year occurring during the typical RSV season. In addition, as suggested by the PHIS database, nearly 80% of deaths occurred in children with complex chronic medical conditions. The mean age at time of death was 7.5 months for infants in the PHIS data set and 6.2 months in the KID data set.¹⁵

An industry-sponsored meta-analysis of published reports of fatality rates attributable to RSV infection in children suggested higher rates of death based on estimates from earlier years, likely because supportive care received in intensive care units was less effective in earlier years.¹⁰⁶

A statistically significant reduction in RSV mortality has not been demonstrated in any randomized clinical trial with palivizumab or motavizumab. Thus, inclusion of mortality reduction or life years saved is difficult to justify in a cost analysis of palivizumab prophylaxis.

Motavizumab

Motavizumab is a second-generation monoclonal antibody that differs from palivizumab by 13 amino acids. Motavizumab was developed by affinity maturation of the complementarity determining regions of palivizumab to improve binding affinity to F protein. In cell culture, motavizumab has approximately 10-fold greater neutralizing activity than palivizumab against RSV clinical isolates of both A and B subtypes.¹⁰⁷ Unlike palivizumab, motavizumab may reduce RSV viral load in the upper respiratory tract, as well as the lower respiratory tract.¹⁰⁸

Data from several clinical trials, including a noninferiority trial between palivizumab and motavizumab, were submitted to the FDA as part of the licensing application for motavizumab.^{109–111} In August 2010, the FDA rejected the license application for motavizumab. Among a number of concerns noted by the FDA was lack of greater clinical efficacy from motavizumab and a threefold increase in hypersensitivity reactions among motavizumab recipients relative to palivizumab recipients.^{107,109,112} Methodologic concerns were raised by the FDA in regard to laboratory testing procedures and geographic variation in results from the noninferiority trial. Specifically, the generalizability of the main study finding was uncertain, because the results of the primary end point differed when stratified by geographic location. The results did not reach the noninferiority threshold for the northern hemisphere, where approximately 90% of subjects were enrolled.¹⁰⁷

The overall RSV hospitalization rate was 4.8% among palivizumab recipients in the IMPact-RSV trial compared with a 1.9% RSV hospitalization rate among palivizumab recipients in the palivizumab-motavizumab noninferiority trial. It was concluded that the non-

inferiority trial may have been conducted in a population with less comorbidity than the IMPact-RSV study. The FDA requested an additional clinical trial to support a satisfactory risk–benefit profile in populations for which prophylaxis is being considered.¹⁰⁷

RSV-specific outpatient medically attended lower respiratory tract infections were reported to be significantly lower among motavizumab recipients relative to palivizumab recipients in the noninferiority trial. However, this outcome was determined in a subset of patients from selected study sites, making the risk of bias high, as noted in the FDA report.¹⁰⁷

Outpatient visits among RSV-infected children exceed the number of outpatient visits attributable to influenza infection by more than twofold.¹¹³ One study of acute respiratory infection in children younger than 8 years estimated children from birth through 23 months of age experienced overall emergency department visits attributable to RSV infection at a rate of 64.4/1000 (95% CI, 45.4–91.3) compared with a rate of 15.0/1000 (95% CI, 4.4–50.6) among influenza-infected children (27% had received influenza vaccine) during 2 respiratory virus seasons between 2003 and 2005.¹¹³ The impact of immunoprophylaxis on outpatient medically attended events attributable to RSV infection is an important consideration but remains unknown because of lack of evaluation in a rigorous, controlled fashion.

Palivizumab-Resistant Isolates

Palivizumab and motavizumab bind to a highly conserved epitope (antigenic site A) on the extracellular domain of the mature F protein that encompasses amino acids 262 to 275. After antibody binding, viral entry into the respiratory epithelial cell is blocked, as is cell-to-cell fusion of infected cells.² RSV escape mutants resistant

to palivizumab have been isolated from approximately 5% of children hospitalized with breakthrough RSV infection while receiving monthly palivizumab prophylaxis.^{1* 21,22,23,114} RSV isolates resistant to palivizumab contain mutations in codons encoding the amino acids between 262 and 275 of the F protein. Amino acid sequence variations outside antigenic site A do not appear to confer palivizumab resistance.

Effect of Palivizumab Prophylaxis on Subsequent Wheezing

Numerous studies have documented that infants hospitalized with viral lower airway disease are more likely to experience recurrent wheezing compared with infants who do not experience severe bronchiolitis.^{68,115–119} The possible effect of avoidance of RSV lower respiratory tract infection early in life with palivizumab prophylaxis on recurrent wheezing was addressed in 3 industry-sponsored studies.^{16,17,120}

One trial among preterm infants without CLD describes physician-diagnosed recurrent wheezing in 8% of prophylaxis recipients and in 16% of the control group. This trial was conducted at 27 sites, and the patients were followed for up to 24 months. Participants were not prospectively randomized, the groups were not balanced for birth weight, degree of prematurity or known RSV risk factors, and families were not blinded to study medication, making the results of uncertain significance.¹²⁰

A nonrandomized observational report from Japan compared the incidence of wheezing between 349 preterm infants (33–35 weeks' gestation) who received palivizumab prophylaxis in the first 6 months of life with 95 infants who did not receive prophylaxis. The primary end point of the study was physician-diagnosed wheezing during

a 3-year follow-up. Twenty-two of 345 infants (6.4%) who received immunoprophylaxis experienced wheezing, whereas 18 of 95 infants (18.9%) who did not receive prophylaxis developed recurrent wheezing ($P < .001$) during the 3-year follow-up period.¹⁷ No difference in hospitalization rates attributable to respiratory disease between the 2 groups was found. Concerns with this study design include the lack of randomization and blinding and the absence of standardized enrollment criteria at the 52 participating sites, each of which may have led to enrollment bias, and no information was provided on the severity of the wheezing episodes. In addition, a history of smokers in the household and family history of allergy was significantly more common in the untreated group.

A double-blind placebo-controlled trial conducted in the Netherlands addressed palivizumab prophylaxis and recurrent wheezing using a different study design.¹⁶ Parent-reported wheezing in 429 otherwise healthy late preterm infants during the first year of life was evaluated in 214 infants who received monthly prophylaxis with palivizumab compared with 215 infants who received placebo. During the first year of life, infants and young children in the placebo group experienced 2309 days with wheezing from a total 51 726 patient days (4.5%), whereas those in the palivizumab group had 930 days of wheezing of 53 075 patient days (1.8%; $P = .01$). This represents an absolute 2.7 fewer days of wheezing per 100 patient days (17.5 wheezing days/1000 days vs 44.6 wheezing days/1000 days or 27.1 fewer wheezing days/1000 days) among infants who received monthly palivizumab in contrast to those who did not receive prophylaxis.¹⁶ Reliance on parent reporting of wheezing was identified as a potential limitation. The wheezing episodes were not

medically attended events but parent-reported wheezing of unknown severity.¹⁶ The proportion of infants using bronchodilators in the placebo group was 23% and 13% among palivizumab recipients.

Cost Analyses

Financial stewardship is a concept that acknowledges a physician's responsibility to advocate "for a just and cost-effective distribution of finite resources."^{121,122} Use of noncost-effective interventions contribute to maladies within the health care system, including huge deficits, lower quality of care, and inequitable access to health care.¹²³ Financial stewardship has become an essential component of successful reform of the existing health care system.

A number of economic analyses from different countries have evaluated immunoprophylaxis use in different age groups, among children with varying comorbidities and from both the payer and the societal perspective.²⁴ Economic evaluations sponsored by the manufacturer of palivizumab suggest cost neutrality or even cost savings.^{124–134} In contrast, analyses conducted by independent investigators consistently demonstrate the cost of palivizumab prophylaxis far exceeds the economic benefit of hospital avoidance, even among infants at highest risk.^{24,25,39–42,46,90,135–143} Variation in results are explained by differences in study methodology and different base case assumptions used in the model, such as incidence of RSV hospitalization for different risk groups, effectiveness of prophylaxis in reducing hospitalization rate by risk group, estimates of cost of prophylaxis and RSV hospitalizations avoided, number of doses administered, estimated age and weight of infants, and inclusion of a theoretical benefit on mortality reduction.

The CDC has recommended quality-adjusted life years (QALYs) saved as an optimal approach to evaluate the benefit of an intervention. One analysis using this methodology for hypothetical cohorts of infants without CLD born at 26 to 32 weeks' gestation revealed the incremental cost-effectiveness ratio to be greater than \$200 000 per QALY saved for all gestational ages, a figure not considered to be cost-effective.¹³⁵

An economic analysis funded by the manufacturer of palivizumab and published in the *Journal of Medical Economics* also examined incremental cost-effectiveness ratios per QALY gained in 4 groups of preterm infants without CLD and revealed the cost of treatment with palivizumab for infants 32 to 35 weeks' gestation with ≤ 1 risk factor was \$464 476, using an average cost for palivizumab for private and public payers. Medicaid discounts were reported to have resulted in an "approximate 40% reduction in palivizumab cost for approximately 60% of palivizumab recipients."¹²⁹ Nonetheless, in most state Medicaid programs, palivizumab is one of the most costly medication expenditures.

Cost was considered during deliberations by the COLD and the Bronchiolitis Guidelines Committee, but the final guidance as presented in the accompanying Policy Statement is driven by the limited clinical benefit derived from palivizumab prophylaxis.

The American College of Physicians Clinical Guidelines Committee outlines principles to help clinicians define high-value health care by considering key concepts: benefits, harms and cost of the intervention, downstream costs that occur as a result of the intervention, and finally, the incremental cost-effectiveness ratio.¹⁴⁴ On the basis of these principles, the minimal clinical reduction in RSV hospitalizations and reduction in wheezing

episodes associated with palivizumab prophylaxis are not of sufficient clinical and societal importance to justify the cost. Although some RSV hospitalizations may be severe and prolonged, the majority of hospitalizations generally last 2 to 3 days. The high cost of palivizumab prophylaxis becomes a cost-inefficient way to prevent a few short hospitalization stays and a small number of longer hospital stays, especially in the absence of evidence of significant long-term benefit and no measurable effect on mortality.¹⁴⁴

Health expenditures should not be based only on cost and benefit but rather on the assessment of the benefit of the intervention relative to the expenditure. High-cost interventions may be appropriate if highly beneficial.¹⁴⁴ Because the high cost of palivizumab prophylaxis is associated with minimal health benefit, this intervention cannot be considered as high-value health care for any group of infants.

Control Measures

A critical aspect of RSV prevention among all infants is education of parents and other caregivers about the importance of decreasing exposure to and transmission of RSV. Preventive measures include limiting, where feasible, exposure to contagious settings (eg, child care centers) and emphasis on hand hygiene in all settings, including the home and the neonatal ICU, especially during periods when contacts of children at high risk have respiratory tract infections. For all children, the importance of breastfeeding, avoidance of crowds, and absence of exposure to tobacco smoke, including second-hand and third-hand exposure, should be emphasized.

Future Possibilities

Continued evaluation of the impact of palivizumab prophylaxis should include other groups considered to be

at increased risk of disease to evaluate reductions in RSV hospitalizations, as well as the effect of prophylaxis on medically attended outpatient visits.

Investigation of other types of passive immunoprophylaxis including anti-G monoclonal antibodies, should continue not only in prophylaxis but in treatment studies to modulate RSV disease severity.¹⁴⁵ Modification of the Fc fragment of the motavizumab molecule appears to prolong the half-life and theoretically may enable administration of fewer doses of motavizumab per season, although an increased risk of adverse effects remains a concern.^{107,146} Nanobodies are antibody-derived proteins consisting of functional heavy-chain antibodies that lack light chains and were initially found in camels and llamas. Nanobodies directed against the RSV fusion protein have demonstrated RSV-neutralizing activity in experimental models.¹⁴⁷

Ribavirin was licensed in 1986 and remains the only FDA-licensed antiviral agent for therapy but seldom is used because of limited efficacy, cumbersome delivery (aerosol), and high cost.⁵ Interest continues in developing more broadly effective antiviral agents including fusion inhibitors and small interfering RNA.^{148,149}

Development of a safe and effective RSV vaccine remains a high priority.^{150–153} Progress has been achieved with live-attenuated intranasal vaccines,¹⁵⁴ but ensuring adequate attenuation while maintaining immunogenicity remains a challenge. Early experience with a formalin-inactivated whole virus vaccine resulted in enhanced RSV disease in young children in the 1960s, which has complicated development of inactivated RSV vaccines.^{150,155} The demonstration of the effectiveness of passive prophylaxis with an anti-F monoclonal provides reassurance that antibody to the F protein is protective. New

subunit vaccines and particularly vaccines directed against the F protein administered intramuscularly or intranasally continue to be explored.^{150,155} A vaccine against a “prefusion” configuration of the F protein may offer increased efficacy with less risk of disease enhancement.¹⁵⁶ F protein viral-like particle vaccines administered during the latter half of pregnancy might offer passive protection for young children through the first months of life.^{157,158}

SUMMARY

The vast majority of RSV hospitalizations occur among healthy term infants. Immunoprophylaxis remains an option for a very small number of children, but palivizumab immunoprophylaxis will continue to have only a minimal effect on the burden of RSV disease. Effort should be made to avoid prophylaxis among infants and young children who do not qualify for prophylaxis, as outlined in the accompanying AAP policy statement.⁶

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Updated Recommendations on the Use of Meningococcal Vaccines

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- *Policy Statement*

POLICY STATEMENT

Updated Recommendations on the Use of Meningococcal Vaccines

abstract

FREE

Since the last policy statement from the American Academy of Pediatrics (AAP) concerning meningococcal vaccine was published in 2011, 2 meningococcal conjugate vaccines have been licensed for use in infants (Hib-MenCY-TT and MenACWY-CRM). The Centers for Disease Control and Prevention (CDC) has published new recommendations, "Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices," which have been endorsed by the AAP. However, the CDC recommendations were published before licensure of MenACWY-CRM for infant use. This policy statement updates the AAP recommendations for use of meningococcal vaccines in children and adolescents. A more comprehensive review of background and technical information can be found in the CDC publication. *Pediatrics* 2014;134:400–403

Neisseria meningitidis is responsible for a spectrum of infections, such as meningitis, bacteremia, and pneumonia, and may be associated with long-term sequelae and death. Five serogroups of *N. meningitidis* (A, B, C, W, and Y) are responsible for the vast majority of disease in children and adults. Specific meningococcal serogroups appear to cause a preponderance of disease in certain age groups and geographic areas. For example, in the United States, *N. meningitidis* serogroup B is predominant in children younger than age 5 years, whereas serogroups C and Y are responsible for the majority of cases in adolescents. *N. meningitidis* serogroup A is hyperendemic in sub-Saharan Africa (the so-called "meningitis" belt) but it is rarely diagnosed in the United States.

For unknown reasons, the incidence of meningococcal disease has decreased in the United States since the late 1990s. The decrease started before the availability of the meningococcal conjugate vaccine and recommendations for routine meningococcal vaccine use in adolescents. Declines in incidence have occurred in all serogroups, including serogroup B, which is currently not included in any meningococcal vaccine licensed in the United States.

In the United States, 4 licensed meningococcal vaccines are available. One is a quadrivalent (A, C, W-135, Y) polysaccharide vaccine (MPSV4 [Menomune, Sanofi Pasteur, Inc, Swiftwater, PA]). There are 2 quadrivalent conjugate vaccines (A, C, W, Y) (MenACWY-D [Menactra, Sanofi Pasteur, Inc] and MenACWY-CRM [Menveo, Novartis Vaccines and Diagnostics, Inc, Cambridge, MA]), and 1 bivalent (C; Y) conjugate vaccine (HibMenCY-TT [MenHibrix, GlaxoSmithKline Biologicals, Research Triangle Park, NC]), which is also approved as a vaccine for *Haemophilus influenzae* type b (Table 1).

COMMITTEE ON INFECTIOUS DISEASES

KEY WORDS

meningococcus, meningococcal vaccine, adolescent vaccines, immunization schedule

ABBREVIATIONS

AAP—American Academy of Pediatrics

CDC—Centers for Disease Control and Prevention

Hib—*Haemophilus influenzae* type b

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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TABLE 1 Licensed Meningococcal Vaccines: United States, 1981–2013

Formulation	Type	Trade Name	Manufacturer	Licensed (y)	Age Group	Dose(s)	Serogroups
MPSV4 ^a	Polysaccharide	Menomune	Sanofi Pasteur	1981	≥2 y	Single dose	A, C, W, and Y
MenACWY-D ^b	Conjugate	Menactra	Sanofi Pasteur	2005	11 to 55 y	Single dose	A, C, W, and Y
MenACWY-D ^b	Conjugate	Menactra	Sanofi Pasteur	2007	2 to 10 y	Single dose	A, C, W, and Y
MenACWY-D ^b	Conjugate	Menactra	Sanofi Pasteur	2011	9 to 23 mo	2-dose series	A, C, W, and Y
MenACWY-CRM ^c	Conjugate	Menveo	Novartis	2010	11 to 55 y	Single dose	A, C, W, and Y
MenACWY-CRM ^c	Conjugate	Menveo	Novartis	2011	2 to 10 y	Single dose	A, C, W, and Y
MenACWY-CRM ^c	Conjugate	Menveo	Novartis	2013	2 mo to 2 y	4-dose series	A, C, W, and Y
Hib-MenCY-TT ^d	Conjugate	MenHibrix	GlaxoSmithKline	2012	6 wk to 18 mo	4-dose series	C and Y

^a Package insert available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM308370.pdf>

^b Package insert available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM131170.pdf>

^c Package insert available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM201349.pdf>

^d Package insert available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/Approvedproducts/UCM308577.pdf>

BACKGROUND AND RATIONALE

Meningococcal vaccines are recommended routinely for adolescents and for selected groups of children at increased or persistent risk for invasive meningococcal disease (Table 2). There are 2 types of meningococcal vaccines: (1) polysaccharide and (2) conjugated polysaccharide vaccines. Conjugated polysaccharide vaccines use a T-cell–dependent mechanism that results in a more robust primary immune response and immunologic memory and boosting potential, as compared with polysaccharide-only vaccines that use a T-cell independent mechanism. The new indications and newly licensed vaccines address immunization of younger children at increased risk for meningococcal disease.

This document provides a complete update of policy recommendations of the American Academy of Pediatrics for children and adolescents.

RECOMMENDATIONS

The following are meningococcal vaccination recommendations (Table 3):

- For the pediatric population, an age-appropriate meningococcal conjugate vaccine is preferred to the meningococcal polysaccharide vaccine, unless there is a contraindication for the meningococcal conjugate vaccine.
- Adolescents should be routinely immunized at 11 to 12 years of age and given a booster dose at 16 years of age with a quadrivalent conjugated meningococcal vaccine.
- Adolescents who received their first dose at age 13 to 15 years should receive a booster at age 16 to 18 years at least 8 weeks or up to 5 years after their first dose.
- Adolescents who receive their first dose of meningococcal conjugate vaccine at or after 16 years of age do not need a booster dose.
- Unvaccinated or previously vaccinated first-year college students through age 21 years living in residence halls who received their last dose before their 16th birthday (ie, incompletely vaccinated) should receive a single dose of quadrivalent meningococcal conjugate vaccine.
- For individuals who are at increased risk for invasive meningococcal disease because of persistent complement (eg, C3, C5–C9, properdin, factor H, or factor D) deficiency or functional or anatomic asplenia, a 2-dose primary series (MenACWY-D or MenACWY-CRM) is administered to individuals 2 to 55 years of age, and a 4-dose primary series (MenACWY-CRM or Hib-MenCY-TT) is administered to children 2 to 18 months of age. MenACWY-D can be administered as a 2-dose series to infants 9 to 23 months of age with persistent complement component deficiency, and in infants up to 23 months of age after the fourth dose of the primary pneumococcal conjugate vaccine has been given in children who have functional or anatomic asplenia.
- HIV infection is not an indication for routine MenACWY immunization before 11 years of age. However, HIV-infected children 11 years of age or older should be given a 2-dose primary series 8 to 12 weeks apart (MenACWY-D or MenACWY-CRM) with a single booster dose, consistent with recommendations for healthy adolescents.
- For children older than age 2 years who have persistent risk for meningococcal disease because of complement component deficiency or asplenia, their primary series should include 2 doses of quadrivalent meningococcal conjugate vaccine 8 to 12 weeks apart (MenACWY-D or MenACWY-CRM).
- For children 2 months to 6 years of age at persistent risk for meningococcal disease (Table 2), a booster dose should be given 3 years after the primary series and every 5 years thereafter. For children and adolescents 7 years or older at persistent risk for meningococcal disease (Table 2)

TABLE 2 Children at Increased Risk for Meningococcal Disease

Persistent complement component deficiencies (C3, C5–C9, properdin, factor D, and factor H)
Functional or anatomic asplenia
Travel to or reside in an area with hyperendemic or epidemic meningococcal disease
Residence in a community with a meningococcal outbreak

TABLE 3 Recommended Meningococcal Vaccines by Age Group

Age Group	Vaccine	Routine Recommendation	Dosing Schedule
2 mo to 10 y	MCV4-D (Menactra, Sanofi) ^a	High-risk only ^a High-risk only ^b High-risk only ^c	Primary • Age 9 to 23 mo: 2-dose series with 12 weeks between doses • Age 2 to 10 y: 1 dose Booster (for persons who remain at risk) • First booster 3 y after primary series for children who received primary series before age <7 y, then every 5 y • Every 5 y for children who received primary series after 7th birthday
	MCV4-CRM (Menveo, Novartis)		Primary • Age 2 to 6 mo: 4 doses at 2, 4, 6, and 12 mo • Age 7 to 23 mo: 2 doses should be given, with the 2nd dose given in the 2nd year of life • Age 2 to 10 y: 1 dose Booster (for persons who remain at risk) • First booster 3 y after primary series for children who received primary series before age <7 y, then every 5 y • Every 5 y for children who received primary series after 7th birthday
	HibMenCY-TT (MenHibrix, GSK)		Primary • Age 2 to 18 mo: 4-dose series with doses at 2, 4, 6, and 12 to 15 mo Booster (for persons who remain at risk) • Use MCV4-D or MCV4-CRM (see above)
11 to 21 y	MCV4-ACWY-D (Menactra, Sanofi)	Healthy and high-risk	Primary: healthy • Age 11 to 15 y: 1-dose primary series with booster at 16 to 21 y • Age 16 to 21 y: 1 dose, no booster necessary Booster: healthy • Age 16 to 21 y: 1 dose Primary: high risk • 2-dose primary series for those who have asplenia, HIV infection, or persistent complement component deficiency Booster (for persons who remain at risk) • First booster 3 y after primary series for children who received primary series before age <7 y, then every 5 y • Every 5 y for children who received primary series after 7th birthday
	MCV4-ACWY-CRM (Menveo, Novartis)	Healthy and high risk	Primary: healthy • Age 11 to 15 y: 1-dose primary series with booster at 16 to 21 y • Age 16 to 21 y: 1 dose, no booster necessary Booster: healthy • Age 16 to 21 y: 1 dose Primary: high risk • 2-dose primary series for those who have asplenia, HIV infection, or persistent complement component deficiency Booster (for persons who remain at risk) • First booster 3 y after primary series for children who received primary series before age <7 y, then every 5 y • Every 5 y for children who received primary series after 7th birthday
	HibMenCY-TT (MenHibrix, GlaxoSmithKline)	Not approved for this age group	

^a For children who have complement component deficiency or functional or anatomic asplenia or who are part of a community or organizational outbreak or who are traveling internationally to a region with hyperendemic or endemic meningococcal disease. For infants receiving the vaccine before travel, the 2 doses may be administered as early as 8 weeks apart. Infants who have functional or anatomic asplenia should wait until 2 years of age to prevent immune interference with PCV13.

^b For children who have complement component deficiency or functional or anatomic asplenia, or who are part of a community or organizational outbreak or who are traveling internationally to a region with hyperendemic or endemic meningococcal disease.

^c For children who have complement component deficiency or functional or anatomic asplenia, or who are part of a community or organizational outbreak. Hib-MenCY-TT is not recommended for use in children who are traveling internationally to a region with hyperendemic or endemic meningococcal disease. MCV4 should be used as booster doses for children who are given a primary series with Hib-MenCY-TT.

whose initial meningococcal vaccination was administered at 7 years or older, boosters of quadrivalent meningococcal conjugate should be repeated every 5 years (Table 4).

SPECIAL CIRCUMSTANCES

Routine vaccination against meningococcal disease is not recommended for healthy children 2 months to 10 years of age unless they are at increased or persistent

risk for meningococcal disease (Table 2). Hib-MenCY-TT (MenHibrix) may be administered to any infant for routine vaccination against *Haemophilus influenzae* type b (Hib). If Hib-MenCY-TT is used for

TABLE 4 Schedule for Booster Doses in Individuals Who Have Persistent Increased Risk for Invasive Meningococcal Disease

Age at Last MCV4 Dose	Duration Until Next Booster Dose
2 mo to 6 y	3 y ^a
>6 y	5 y

^a If last dose was HibMenCY-TT, the booster dose should be MenACWY-D or MenACWY-CRM.

protection against meningococcal disease, it should be used for all 4 doses of Hib vaccine, and other Hib-containing vaccines should not be used.

Limited data suggest that different conjugate vaccine products can be used interchangeably. If the same vaccine product used for the first dose is not available or if it is not known which vaccine product was used previously, administration of the vaccine should not be deferred if indicated, and any licensed age-appropriate conjugate vaccine can be administered.

The meningococcal vaccine is not routinely recommended for HIV-infected children until they reach 11 years of age, similar to other non-HIV-infected adolescents. HIV-infected children should receive 2 doses as their primary series.

A primary series consisting of 2 or more doses (depending on the age of the child) is indicated for children who have asplenia (reduced antibody response after a single primary dose) and complement component deficiency (higher antibody levels are needed for bacterial clearance mechanisms, such as opsonization, and more rapid antibody waning).¹

For travelers to areas with high meningococcal endemicity (parts of sub-Saharan Africa [the so-called “meningitis belt”] or the Hajj in Saudi Arabia), an age-appropriate meningococcal

vaccine that includes serogroups A and W is indicated. Periodically, there may be other areas in the world with meningococcal outbreaks (eg, serogroup W in Chile). Travelers need to monitor this possibility. Completion of the entire series is preferred before travel as follows: (1) for children <9 months of age: 2, 4, and 6 months of age (with booster at 12 to 18 months of age) with MenACWY-CRM; (2) for children ≥9 months to 23 months of age: 2 doses separated by at least 8 weeks (MenACWY-D) or 2 doses separated by at least 3 months (Menveo); and (3) for people >24 months of age: a single dose (MenACWY-D or MenACWY-CRM).

Pregnancy and breastfeeding do not preclude vaccination with MenACWY (Menactra or Menveo) or MPSV4 (Menomune) if indicated.

PRECAUTIONS AND CONTRAINDICATIONS

Vaccination with any meningococcal vaccine is contraindicated in people known to have a severe allergic reaction to any component of the vaccine. Conjugate vaccines that contain diphtheria or tetanus toxoid are contraindicated in people who have severe allergic reactions to these toxoids. A history of Guillain-Barré syndrome is not a contraindication or precaution for meningococcal vaccination. A previous temporal relationship between MenACWY-D and Guillain-Barré syndrome was not determined to be causally related. All currently licensed meningococcal vaccines are inactivated. They can be administered to people who are immunosuppressed as a result of disease or medication. However, the response to meningococcal vaccine in immunosuppressed children may be less than optimal.

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Withholding or Termination of Resuscitation in Pediatric Out-of-Hospital Traumatic Cardiopulmonary Arrest

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- *Policy Statement*

POLICY STATEMENT

Withholding or Termination of Resuscitation in Pediatric Out-of-Hospital Traumatic Cardiopulmonary Arrest

abstract

FREE

This multiorganizational literature review was undertaken to provide an evidence base for determining whether recommendations for out-of-hospital termination of resuscitation could be made for children who are victims of traumatic cardiopulmonary arrest. Although there is increasing acceptance of out-of-hospital termination of resuscitation for adult traumatic cardiopulmonary arrest when there is no expectation of a good outcome, children are routinely excluded from state termination-of-resuscitation protocols. The decision to withhold resuscitative efforts in a child under specific circumstances (decapitation or dependent lividity, rigor mortis, etc) is reasonable. If there is any doubt as to the circumstances or timing of the traumatic cardiopulmonary arrest, under the current status of limiting termination of resuscitation in the field to persons older than 18 years in most states, resuscitation should be initiated and continued until arrival to the appropriate facility. If the patient has arrested, resuscitation has already exceeded 30 minutes, and the nearest facility is more than 30 minutes away, involvement of parents and family of these children in the decision-making process with assistance and guidance from medical professionals should be considered as part of an emphasis on family-centered care because the evidence suggests that either death or a poor outcome is inevitable. *Pediatrics* 2014;133:e1104–e1116

INTRODUCTION

In 2003, the National Association of EMS Physicians and the Committee on Trauma of the American College of Surgeons published guidelines for out-of-hospital withholding or termination of resuscitation for adult victims of traumatic cardiopulmonary arrest who met specific criteria.¹ Clinical criteria included absent pulse, unorganized electrocardiogram rhythm, fixed pupils (all at the scene), and cardiopulmonary resuscitation (CPR) greater than 15 minutes. The recommendations did not extend to the pediatric population. Although many of the studies on which the recommendations were based included children, the vast majority of the involved subjects were adults. Studies published to that time that addressed the pediatric population in particular^{2,3} and evaluated survival and functional outcome of pediatric blunt trauma victims with either full traumatic cardiopulmonary

AMERICAN COLLEGE OF SURGEONS Committee on Trauma, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS Pediatric Emergency Medicine Committee, NATIONAL ASSOCIATION OF EMS PHYSICIANS, and AMERICAN ACADEMY OF PEDIATRICS Committee on Pediatric Emergency Medicine

KEY WORDS

traumatic cardiopulmonary arrest, blunt trauma, cardiorespiratory arrest, resuscitative thoracotomy, out-of-hospital cardiac arrest, out-of-hospital termination of resuscitation, cardiopulmonary resuscitation, emergency medical services, advanced life support, basic life support, outcome, survival, children, adolescent

ABBREVIATIONS

CPR—cardiopulmonary resuscitation
ED—emergency department
EMS—emergency medical services
PCPC—pediatric cerebral performance category
ROSC—return of spontaneous circulation

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(Continued on last page)

arrest or severe hypotension suggested that the prognosis for pediatric traumatic cardiopulmonary arrest victims is similar to that for adults. Given the emotional demands of withholding resuscitation from a child in the field, it was believed by both the leadership in pediatric trauma care and emergency medical services (EMS) that additional studies were warranted before including children in any termination-of-resuscitation protocol. This literature review in pediatrics was undertaken to provide an evidence base for determining whether recommendations for out-of-hospital termination of resuscitation could be made. The project aims were to (1) identify whether specific criteria exist that would support out-of-hospital withholding or termination of resuscitation for traumatic cardiopulmonary arrest victims and (2) identify a specific time frame for any subset of pediatric trauma patients beyond which further resuscitative efforts are futile.

METHODS

Organizational participants included the Committee on Trauma, Subcommittee on Emergency Services—Prehospital, and Pediatric Surgical Specialty Group of the American College of Surgeons; Committee on Pediatric Emergency Medicine of the American Academy of Pediatrics; National Association of EMS Physicians; and Pediatric Committee of the American College of Emergency Physicians. The initial review was completed in September 2008, and additional literature through 2011 was added to provide currency to the review. General guidelines for evaluation included the following:

1. Distinguish between blunt and penetrating trauma victims.
2. Define “pediatric patient” as 18 years of age or younger.
3. Determine location of arrest (out-of-hospital or emergency department [ED]).

Specific characteristics of the arrest were determined, if possible, as follows:

1. Distinguish between respiratory and cardiopulmonary arrest (from any cause).
2. Determine duration of witnessed arrest.
3. Determine duration of resuscitation to successful return of spontaneous circulation (ROSC).
4. Determine outcome of children who had successful ROSC: did they survive to reach the hospital, survive to hospital discharge, and have long-term neurologic function?
5. Determine duration of resuscitation efforts in nonsurvivors.
6. Determine effects of epinephrine administration.
7. Determine outcome of thoracotomy when used.
8. Exclude special circumstances: drowning (warm or cold water), hypothermia, burns, electrocution (lightning, electric fence).
9. Determine any caveats with regard to survival to be an organ donor.

Methodology for the evidence evaluation was based on the 2000 Eastern Association for the Surgery of Trauma guideline “Utilizing Evidence-Based Outcome Measures to Develop Practice Management Guidelines: A Primer.”⁴ Class I evidence is derived from prospective, randomized, controlled trials; class II evidence represents clinical studies in which data were collected prospectively or retrospective analyses that were based on clearly reliable data; and class III evidence is based on retrospectively collected data. A validity scale for class I was detailed by Jadad et al in 1996.⁵ Recommendations were classified as level 1, 2, or 3 according to the following definitions:

1. Level 1: The recommendation is convincingly justifiable based on the available scientific information alone. This recommendation is usually based on class I data; however, strong class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, low-quality or contradictory class I data may not be able to support a level 1 recommendation.
2. Level 2: The recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert opinion. This recommendation is usually supported by class II data or a preponderance of class III evidence.
3. Level 3: The recommendation is supported by available data, but adequate scientific evidence is lacking. This recommendation is generally supported by class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

Each article was assigned at least 2 reviewers. The assignments were known only to the project director. All articles were also reviewed by the project director, and evidence class was reconciled as needed.

LITERATURE REVIEW

MedLine and PubMed were searched for the initial review through Ovid from 1980 to 2006. Subsequently, the review was updated with literature as recent as 2011. Search terms included traumatic cardiopulmonary arrest, blunt trauma, cardiorespiratory arrest, resuscitative thoracotomy, out-of-hospital cardiac arrest, out-of-hospital termination of resuscitation, cardiopulmonary resuscitation, EMS, advanced life support, basic life support, outcome, survival, children, and adolescent. Article

bibliographies were hand-searched for additional references. New citations were added and assigned as appropriate. Abstracts were included only if a companion manuscript was identified. Editorials, letters to the editor, and studies that included only adults were eliminated. Published articles that included only victims of drowning were ultimately eliminated after review because the special circumstance of hypothermia and/or cold water drowning may alter resuscitation. Studies that included both adults and children were used if the children were evaluated separately or if data relevant only to children could be abstracted from the text. Studies that mixed traumatic arrests and arrests from other causes were used only if the trauma cohort was described independently. Only trauma patients who suffered a cardiopulmonary arrest rather than isolated respiratory arrest were included. Individual patients were included for review only if they could be tracked through the published article such that some outcome (ie, at least survival to hospital discharge) could be determined. The arrest interval or time to resuscitation was defined, in a witnessed arrest, as the time between the occurrence of arrest and the time that CPR was instituted, whether by a bystander or professional. Resuscitation time was defined as the duration of CPR until either ROSC or death was declared.

RESULTS

Fifty-four articles were retrieved for the initial review.^{2,3,6-57} Of these, 35 were eliminated for the reasons described previously,⁶⁻⁴⁰ leaving 19 articles with potentially useful information.^{2,3,41-57} An additional 23 articles were screened for the secondary review,⁵⁸⁻⁸¹ with 9 articles appropriate for inclusion.^{58,64-69,72,81} There were 2 sets of patients included in 2 articles each, and data were used only once.^{53,72,74,80} There were 5 class II studies and 22 class III studies.

From the 27 articles, there were 1114 patients who suffered an out-of-hospital traumatic cardiopulmonary arrest, with 60 surviving to hospital discharge (5.4%). Outcome data were available in 23 articles for 51 of these patients (Table 1): 29 suffered neurologic devastation and were either severely disabled or in a vegetative state,^{2,6,41,44,53,64,66,68} 3 patients had moderate disability,^{3,42,66} and 19 survived with a "good" or full neurologic recovery.^{3,42,66,68,69} A separate evidentiary table provides data for cases of out-of-hospital traumatic cardiopulmonary arrest in children for which outcome was not reported (Table 2).^{56,59,72,81}

A uniform system of describing disability was not used by all authors, although the most popular system was the pediatric cerebral performance category (PCPC; Table 3).⁸² Thirty-six patients suffered an out-of-hospital traumatic cardiopulmonary arrest from penetrating injuries, and at least 9 of them had a resuscitative thoracotomy in an ED; all of these patients died regardless of whether thoracotomy was performed.^{3,50-52,68} Resuscitative thoracotomy was performed at the scene, in the ED, or in the operating room, for 30 patients (combined blunt and penetrating trauma victims) who suffered an out-of-hospital traumatic cardiopulmonary arrest, and there were no survivors.^{3,50-52} A few published articles mentioned children who were declared dead in the field, implying that the state or country has a do-not-resuscitate protocol for a subset of arrest victims.^{3,47,48,78,79}

Cause of death, interval of arrest to CPR, and total resuscitation time for survivors were reported in a few articles. Specific anatomic causes of death were only rarely mentioned in published articles and included blunt trauma to the brain and spinal cord⁴³ and penetrating injuries to the head/brain, liver,

spleen, heart, and aorta.⁵⁰ In a recent report, 78% of nonsurvivors had a traumatic brain injury.⁶⁶ It was difficult to abstract time to initiation of resuscitation and total resuscitation times for trauma patients from most articles. Information for arrests of all causes was available in a few. For example, interval to CPR was 2.3 minutes for survivors and 6.5 minutes for nonsurvivors in a Canadian study of 41 patients who had an unexpected cardiac arrest,⁴⁸ and median interval to initiation of CPR in a prospective study from California that included arrests from all causes was 3 minutes (range, 0-5 minutes) among survivors and 13 minutes (range, 4-64 minutes) among nonsurvivors.⁵³ Reported survivor mean ED resuscitation time in 1 article, exclusive of field resuscitation, was 11.4 minutes,⁴² and survivor median resuscitation time in another report was 14 ± 2.5 minutes (in the ED).⁴⁵ One article further described 5 survivors with a mean resuscitation time in the ED of 57.8 (SD, 25.5 minutes), and all had either severe disability or a vegetative state at discharge.⁴¹ An outlier survivor in terms of resuscitation time had a good outcome with a combined 42 minutes of out-of-hospital and ED resuscitation.⁴⁵ In a study describing 56 pediatric patients with out-of-hospital traumatic cardiopulmonary arrest, 20 of the 56 trauma patients were revived by initial in-hospital CPR (ROSC, ≥ 20 minutes), but only 1 patient whose outcome was not disclosed was eventually discharged from the hospital alive.⁵⁸ In 2010, a retrospective review of pediatric out-of-hospital traumatic cardiopulmonary arrest documented 6 survivors of a patient cohort of 30 patients.⁶⁶ CPR greater than 15 minutes and fixed pupils distinguished nonsurvivors from survivors, and adult criteria based on those of Hopson et al¹ correctly predicted 100% of those who died when all of the criteria were met. The mean duration of CPR was 42

TABLE 1 Evidentiary Table for Out-of-Hospital Traumatic Cardiopulmonary Arrest in Children Where Outcome Was Reported

Authors	No. of Trauma Victims	Survivors	Outcome	Special Circumstances	Class
Hazinski et al 1994 ²	38	1	Severe disability (9.5-y-old functioning as nonambulatory 1-y-old)	Out-of-hospital intubation did not influence likelihood of reanimation	II
Suominen et al 1998 ³	28	1	Moderate disability	Run over by train, airway obstructed, spontaneous circulation within 17 min of the accident and after 5 min of resuscitation	III
Pitetti et al 2002 ⁴¹	53	1	Severely disabled (PCPC 4; see Table 3)	Survivors likely to be in sinus rhythm on arrival in ED, to have received fewer doses of epinephrine in ED	III
Kuisma et al 1995 ⁴²	10	1	Partial disability, capable of self-care (Bloom III; see Table 2)	Mean resuscitation times for survivors and nonsurvivors was 11.4 and 30.6 min; bystander initiated related to favorable outcome, survivor had ROSC in 17 min	III
Calkins et al 2002 ⁴³	16	0			III
Ronco et al 1995 ⁴⁴	26	1	Severely disabled (examined by a neurologist, no scoring system)	Median ED resuscitation time for both survivors and nonsurvivors was 30 min; only intact survivor was resuscitated before ED arrival	III
O'Rourke, 1986 ⁴⁵	10	2	Vegetative state		III
Thompson et al 1990 ⁴⁶	28	2	Severely disabled		III
Tsai and Kalisen, 1987 ⁴⁷	6	0			III
Friesen et al 1982 ⁴⁸	13	0		Interval between arrest and institution of active CPR was 2.3 min in survivors and 6.5 min in nonsurvivors	II
Sirbaugh et al 1999 ⁴⁹	44	0			II
Sheikh and Culbertson 1993 ⁵⁰	13	0		All had ED thoracotomy within 5 min of ED arrival	III
Beaver et al 1987 ⁵¹	17	0		All had ED thoracotomy after a mean of 22 min of conventional resuscitation	III
Powell et al 1988 ⁵²	9	0		All had ED thoracotomy; all scene arrest patients died	III
Young et al 2004 ⁵³ (same as Brindis et al 2011 ⁸⁰)	118	6	All severe disability or vegetative state (PCPC 4 or 5)	No survivor who had ED CPR >31 min had a good neurologic outcome	II
Patterson et al 2005 ⁵⁴	59	0		No long-term trauma survivors with use of either standard or high-dose epinephrine	II
Martin et al 2002 ⁵⁵	7	0		All patients in study had pulseless electrical activity at scene	III
Broides et al 2000 ⁵⁷	7	0			III
Widdel et al 2010 ⁶⁹	30	1	Good neurologic outcome	Survivor had 2 min of out-of-hospital CPR; aggressive resuscitation is rarely successful	III
Horisberger et al 2002 ⁶⁵	16	0			III
Capizzani et al 2010 ⁶⁶	30	6	2 with good neurologic outcome, 1 fair, 3 poor	CPR >15 min and fixed pupils were predictive of death or poor outcome	III
Fisher and Worthen 1999 ⁶⁴	65	1	1 survivor in persistent vegetative state		III
Murphy et al 2010 ⁶⁸	169	28	55% survived intact but one-third of these required no airway support	66 patients transferred from another hospital; no children survived if CPR was ongoing at ED arrival	III
Total	812	51 (6.3%)		29 (57%) severe disability; 3 (6%) moderate disability; 19 (37%) normal	

minutes (SD, 28 minutes) for nonsurvivors and 7 minutes (SD, 3 minutes) for survivors. Three patients were discharged from the hospital with orders for outpatient rehabilitation services, and 3 patients required extensive rehabilitation and require 24-hour assistance

with activities of daily living. A recently published multicenter cohort study of out-of-hospital pediatric cardiac arrest included 15 children with traumatic cardiopulmonary arrest (total, 138 patients), and 3 survived.⁶⁷ Although PCPC scores were used for

survivors, it was not possible to determine outcomes for these 3 children. However, survivors from all causes had a median duration and interquartile range of CPR of 18.5 minutes (3.5–28.5 minutes) versus 41 minutes (24–54 minutes) for nonsurvivors.

TABLE 2 Evidentiary Table for Out-of-Hospital Traumatic Cardiopulmonary Arrest in Children for Whom Outcome Was Not Reported

Authors	No. of Trauma Victims	Survivors	Outcome	Special Circumstances	Class
Lin et al 2007 ⁵⁸	56	1	Outcome not reported	20/56 patients revived in ED with ROSC all ≥ 20 min	III
Li et al 1999 ⁵⁶	182	2	Unable to determine	National Pediatric Trauma Registry data, <2% of patients who were asystolic on admission were discharged alive	III
Moler et al 2011 ⁷² (same as Moler et al 2009 ⁷⁴)	15	3	Unable to determine	Median duration and interquartile range of CPR of 18.5 (3.5–28.5) min	III
Stockinger et al 2004 ⁸¹	49	3	Unable to determine		III
Total	302	9 (3%)			

TABLE 3 Disability Scoring Systems

PCPC ⁵⁷	
1	Normal
2	Mild disability
3	Moderate disability
4	Severe disability
5	Coma or vegetative state
6	Brain dead
Bloom Classification ⁹²	
I	No disability, active life
II	Mild disability, active life
III	Partial disability, but capable of self-care
IV	Total disability, incapable of self-care

A few articles addressed the use of epinephrine in out-of-hospital cardiopulmonary arrest in terms of survival, with some noting that survivors often needed no epinephrine. At least 3 authors associated more than 2 or 3 doses of standard dose epinephrine with death, although not necessarily among trauma victims, and 1 had survivors who had received up to 4 doses.^{35,41,53,67}

The mean attempted resuscitation time in many studies averaged 30 minutes. Most child survivors of out-of-hospital traumatic cardiopulmonary arrest undergoing resuscitative efforts of this duration were neurologically devastated. The 3 patients who had moderate disability had ROSC after approximately 17 minutes of CPR.^{3,42,66} Normal outcome was seen more often in trauma victims who had a perceived rapid ROSC, although an exact time in minutes was difficult to extract from the article with the majority of survivors who had a normal neurologic status.⁶⁸

A few articles made specific reference to organ donation, mentioning that sustained ROSC may serve as a bridge to possible organ donation and is necessary to prevent organ failure before harvesting.⁵⁸ However, it was noted by another group that it is ethically inappropriate to proceed with resuscitation solely to preserve organs because the physician may be more committed to the potential well-being of an unknown recipient rather than the patient at hand or his or her family members. Traditionally, cadaveric organ transplantation operates under the “dead donor rule,” and organ recovery must not be the direct cause of the donor’s death, a concept that is justified by the prohibition against the direct killing of innocent persons. Furthermore, the added expense associated with organ preservation, until such time as decoupling has occurred and the family can be approached about donation, is generally the responsibility of the donor family. If the family decides to donate, future expenses will be born by the organ procurement organization on behalf of the recipient.⁸³ If the family declines the opportunity to donate, this added expense and burden is not offset by a perceived benefit to the family.⁴⁴

DISCUSSION

Each year in the United States, 16 000 children suffer cardiopulmonary arrest.⁵⁹ Inpatient results are improving,

but the outcome for pediatric traumatic out-of-hospital arrests remains poor, although newer evidence suggests that children and adolescents with out-of-hospital arrest from other causes are more likely to survive than adults.^{41,53,59–62,78,84} Pediatric out-of-hospital deaths represent nearly one-third of pediatric deaths in the United States,⁸⁵ and in 1 urban study, 2% of pediatric EMS calls were attributed to pediatric out-of-hospital arrests.⁶³ Some of the more current studies of out-of-hospital arrest exclude trauma. Trauma is the leading cause of death from 1 through 21 years of age, and homicide or child abuse is the leading cause of trauma in children younger than 1 year⁸⁶; therefore, the optimal management of pediatric out-of-hospital traumatic cardiopulmonary arrest deserves special attention and will be the primary focus of the recommendations based on this review. Because many of the articles used for this review include pediatric arrests with multiple etiologies, making a few general observations about pediatric cardiopulmonary arrest is pertinent.

In a large 3-year prospective study of out-of-hospital arrests attributable to all causes in children younger than 12 years,⁵³ 8.6% of the children survived, one-third of whom had a good neurologic outcome. No patient who received more than 3 doses of epinephrine or more than 31 minutes of resuscitation in the ED survived. In

a more recent review of the literature and science of pediatric resuscitation, Topjian et al reported that 5% to 10% of pediatric out-of-hospital arrest victims survive to hospital discharge, with 0% to 12% having good neurologic outcomes.⁵⁹ Indicators of potential for successful outcomes in pediatric out-of-hospital arrest include a witnessed arrest, the occurrence of early bystander CPR, an initial shockable rhythm, and ROSC within 20 minutes.⁸⁴ In the absence of these characteristics, a good outcome is extraordinarily unlikely. However, anecdotal reports of children who survive after a prolonged resuscitation exist and lend unease to including them in generalized protocols. Although the outcome of pediatric inpatient cardiac arrests, generally associated with primary cardiac disease, is better than for adults, the outcome for pediatric out-of-hospital resuscitation is substantially worse because out-of-hospital arrests in children are more commonly caused by severe trauma, prolonged respiratory arrest, or septic shock rather than a primary cardiac etiology.⁵⁹ These etiologies imply a longer period of hypoxia before the actual arrest, with resulting brain and other organ damage. As noted previously, the mean resuscitation time in most pediatric studies was an average of 30 minutes. Most children with out-of-hospital traumatic cardiopulmonary arrest who received this duration of resuscitation and survived were irreversibly neurologically devastated.^{2,6,41,44,53,64,66,68} Two of the 3 patients who suffered only moderate disability had ROSC after approximately 17 minutes of CPR.^{3,42} Documentation of ROSC for the 19 children who had return to baseline or near-baseline status was reported for only 3 of the children as 2 minutes and less than 15 minutes.^{66,69} In the series that quoted the largest number of intact survivors ($n = 16$),

the authors acknowledged that one-third of survivors presented with a stable airway and did not require intubation for respiratory support. There was also a uniform distribution across all injury severity score groups for survivors, with more than half of those survivors having an injury severity score greater than 16. These findings caused the authors to reflect that almost half of the survivors had either an exceedingly rapid response to out-of-hospital CPR or out-of-hospital findings that may not have warranted CPR intervention at all.⁶⁸ In fact, it has been recognized that some children who undergo CPR in the out-of-hospital setting are unlikely to have been pulseless because of the difficulty of recognizing pulselessness in children.^{60,86}

ED crowding in the United States is an emerging threat to patient safety and public health, particularly in safety-net hospitals.^{88–90} Although the effects of ED crowding on patient care and outcome are complex, transport of a nonviable patient from the field to the ED has the secondary effect of making the resources of the EMS personnel unavailable for those who might benefit from crucial immediate attention. A series of articles by Morrison et al validating the termination of resuscitation rule estimated that the frequency of out-of-hospital adult cardiac arrest transports to the ED could be reduced from 100% to 37.4% of calls, with no loss of viable patients, thus resulting in valuable resource and cost savings.^{91–93} In addition to the cost concerns, the “lights and siren” run is associated with significant potential for injury to EMS personnel and the public.^{94–97} Finally, the costs of supplies (often including precious blood products) and the emotional toll on ED providers who would not

otherwise be exposed to the death, including the risk of posttraumatic stress disorder, are all important considerations that should not be ignored when choosing whether to transport a patient who is already dead or who will inevitably die (unpublished survey data; in process to submit for publication).

It is for these reasons that there is increasing acceptance of termination of resuscitation for adults when there is no hope for a good outcome.^{1,76,91,92,98–101} Although the same justifications apply to children, especially in light of worse out-of-hospital resuscitation outcomes, children are routinely excluded from termination-of-resuscitation protocols, at least in the United States.¹ Approximately half of states have formalized termination of resuscitation in statute or protocol, but only a few apply them to children. In a recent Melbourne, Australian, study of out-of-hospital arrest, 29 patients had attempts at resuscitation discontinued in the field. Including the 7% of patients who had no attempts at resuscitation, this represented 20.6% who were declared dead at the scene by paramedics.⁷⁹

Beyond the resource-saving benefits associated with termination of resuscitation, 2 small studies indicate that families of adult patients who die in the out-of-hospital setting may actually adapt better to their losses when there is cessation of futile resuscitative efforts in the field.^{102,103} Many states have EMS protocols or statutes that allow do-not-resuscitate orders or a declaration of death in the field for adult victims with obvious signs of death, including decapitation, hemicorporectomy, lividity, rigor mortis, and decomposition, although even these states may exclude children from such protocols and procedures. The Resuscitation Outcomes Consortium reported that no EMS resuscitation was performed in 19% of children, and the

Australian reported that no EMS resuscitation was performed in 7%.

There remains a profound reluctance to stop futile resuscitative efforts when the patient is a child.⁹⁸ On the basis of the literature to date, the reluctance stems from provider and public ignorance of out-of-hospital arrest outcomes,^{26–27,29,103–105} fear related to inadequate preparation for communication with acutely grieving family members,^{26,106} perceived determinants of family adaptation to loss, and concerns regarding legal liability for providers. The issue of whether families benefit from futile resuscitative measures in the field and ED has not been studied. The Institute of Medicine study “Emergency Care for Children: Growing Pains”⁹⁰ corroborates that the provision of even routine emergency care for children provokes stress and anxiety for EMS providers because of lack of knowledge, training, and pediatric-specific experience.^{107,108} Increased training and information is desired by EMS providers¹⁰⁹ and seems to mitigate the discomfort in some settings.^{26,29,109,110}

There are no US studies of the needs of families of children at the scene of the death, although it is the time of the most tremendous shock and the time when EMS providers have the unique opportunity to positively affect the lives of the survivors forever. Most existing advice regarding the needs of families affected by the sudden, unexpected death of a child is based on extrapolations from the hospital setting or on anecdotal evidence. These recommendations are remarkably similar to recommendations regarding the care of families bereaved in other settings, particularly when the deceased is a child.^{46,47}

Ethical concerns regarding the implementation of a termination-of-resuscitation policy deserve mention. Minority populations experience

traumatic injuries disproportionately, including traumatic death. Any termination of resuscitation policy may therefore be viewed with distrust, particularly among minority populations. There are situations in which a family is remote from the scene of the arrest, and transport of the child to a hospital may allow family members more resources for grief counseling. EMS providers may be concerned about child abuse and prefer to transport.⁸⁶ New technologies for resuscitation after cardiopulmonary arrest from various causes are being considered and used at some hospitals, including extracorporeal membrane oxygenation.^{111,112} This technology is expensive and may or may not lead to improved neurologic outcomes in trauma patients.¹¹³ The ability of lay parents to grasp the risks and benefits of this extraordinary treatment option, providing informed consent when they are faced with an emergency life-or-death decision for their child, may be significantly compromised by the urgency of the process. The use of hypothermia as a treatment strategy after traumatic brain injury has also been attempted without a demonstrated survival advantage.¹¹⁴ Preservation of circulation with the specific intent of organ preservation for transplantation is controversial. A specific area of debate that applies to this discussion includes the use of invasive procedures that are nonbeneficial to the donor. Health professionals should remain informed of advances in resuscitation that will allow a balanced discussion with those who will have decision-making authority for a given child.

This literature review and analysis has several limitations. The articles available for review are heterogeneous with respect to etiology of arrest, type of arrest (cardiopulmonary versus

respiratory arrest), and location (out-of-hospital or ED), and final outcome data are often lacking. One study used registry data that may repeat reports of some children previously mentioned in the other studies. There is now an effort to try to standardize data for out-of-hospital arrests that will be helpful going forward, but this information cannot be applied to this review.¹¹⁵ One of the more recent reviews that applied this template excluded trauma patients.⁷⁸ Some of the references in the discussion that detail out-of-hospital cardiac arrest transports to the ED in adults may not necessarily translate to children. The original Hopson study has been reconfirmed, and 1 of the pediatric studies used the same criteria with consistent results,^{66,81} but another group had several survivors when applying the same criteria to an urban population.⁷² As mentioned, some children who undergo CPR in the out-of-hospital setting are unlikely to have been pulseless because of the difficulty of recognizing pulselessness in children.^{60,86} Nevertheless, results of the current review suggest that survival for children suffering an out-of-hospital traumatic cardiopulmonary arrest attributable to blunt or penetrating trauma is poor and that many survivors live with devastating neurologic disability. Despite its limitations, the following conclusions can be proposed on the basis of the results of this review: (1) the retrospective analysis revealed a reported overall traumatic cardiopulmonary arrest survival rate of 5.4%; (2) more recent publications corroborate that a short (<20 minutes) ROSC is associated with improved survival but not necessarily a good outcome; (3) virtually all survivors who require resuscitation for >20 minutes are neurologically devastated, but a few children resuscitated under more favorable circumstances have returned

to baseline; and (4) there are some clear markers that will help identify the rare child who might have a chance at a good outcome. In particular, survivors are likely to have a short interval of arrest to CPR (<5 minutes), to have ROSC in the field within minutes of beginning CPR, and to have sinus rhythm on arrival in the ED. There is little evidence that epinephrine makes a difference in the outcome of trauma patients. Most children with out-of-hospital traumatic cardiopulmonary arrest who receive more than 20 minutes of resuscitation and survive are neurologically devastated. Those who do better receive resuscitation for only a few minutes.

Although most of the recommendations in this statement are at a level 2 or 3 based on the evidence, the decision to withhold resuscitative efforts in a child under specific circumstances (decapitation or dependent lividity, rigor mortis, etc) is reasonable. However, in other circumstances, because of the potential for ambiguity and miscommunication, if there is any doubt as to the circumstances or timing of the traumatic cardiopulmonary arrest, under the current status of limiting termination of resuscitation in the field to persons older than 18 years in most states, resuscitation should be initiated and continued until arrival to the appropriate facility. The decision in these instances should not be left to EMS providers with different levels and variety of training, expertise, experience, and communication skills (even with remote input from the medical director, who is not on-site) to ensure a consistent message is delivered to parents and families of these children. If the patient has arrested and resuscitation has already exceeded 30 minutes and the distance to the nearest facility is more than 30 min-

utes away, involvement of parents and family of these children in the decision-making process with assistance and guidance from medical professionals should be considered as part of an emphasis on family-centered care because evidence suggests that either death or a poor outcome is inevitable.

TREATMENT CONCLUSIONS BASED ON EVIDENCE

1. The withholding of resuscitative efforts should be considered in pediatric victims of penetrating or blunt trauma with injuries obviously incompatible with life, such as decapitation or hemicorporectomy (Level 2).
2. The withholding of resuscitative efforts should be considered in pediatric victims of penetrating or blunt trauma with evidence of a significant time lapse after pulselessness, including dependent lividity, rigor mortis, and decomposition (Level 2).
3. Initiation of standard resuscitation should be considered for cardiopulmonary arrest patients in whom the mechanism of injury does not correlate with a traumatic cause of arrest unless (1) or (2) above applies (Level 2).
4. Initiation of standard resuscitation should be considered in cardiopulmonary arrest victims of lightning strike or drowning in whom there is significant hypothermia unless (1) or (2) applies (Level 2).
5. Immediate transportation to an ED should be considered for children who exhibit witnessed signs of life before traumatic CPR and have CPR ongoing or initiated within 5 minutes in the field, with resuscitation maneuvers including airway management and intravenous or intraosseous line

placement planned during transport (Level 2).

6. After blunt and penetrating trauma in victims in whom there is an unwitnessed traumatic cardiopulmonary arrest, a longer period of hypoxia may be presumed to have occurred, and an acceptable duration of CPR (including bystander CPR) of less than 30 minutes may be considered with medical director input (Level 3).
7. If there is any doubt as to the circumstances or timing of the traumatic cardiopulmonary arrest, under the current status of limiting termination of resuscitation in the field to persons older than 18 years in most states, resuscitation should be initiated and continued until arrival to the appropriate facility (Level 3).
8. The inclusion of children in state termination-of-resuscitation protocols should be considered, including children who are victims of blunt and penetrating trauma who have or in whom there is EMS-witnessed cardiopulmonary arrest and at least 30 minutes of unsuccessful resuscitative efforts, including CPR (Level 2).

FUTURE POLICY AND PROTOCOL GUIDANCE

1. Termination-of-resuscitation protocols for children based on the evidence should be developed and implemented under the guidance of the EMS system or state EMS medical director. Online medical control may be needed to determine the appropriateness of termination of resuscitation in individual children.
2. Policies and procedures for termination-of-resuscitation protocols must include notification of the appropriate law enforcement agencies and notification

of the medical examiner or coroner for final disposition of the body.

3. EMS providers should receive education regarding communication with families and assistance with how to direct families to community and grief resources. EMS providers should have immediate access to resources for their own debriefing and counseling. Families of the deceased should have immediate access to culturally and linguistically appropriate care, counseling, and resources, including access to clergy, social workers, and other counseling personnel.
4. EMS, medical control, and ED providers should have access to resources for their own debriefing and counseling after the death of a child.
5. Adherence to policies and protocols governing termination of resuscitation should be monitored through a quality review system.
6. A more formal study evaluating out-of-hospital traumatic cardiopulmonary arrest that includes long-term neurologic and functional outcome should be performed to clarify expectations for intact survival in children and legitimize the inclusion of children in termination-of-resuscitation protocols.
7. Research is vitally needed regarding the acceptance of termination-of-resuscitation protocols by families of children sustaining out-of-hospital traumatic cardiopulmonary arrest to determine the potential emotional effects of both termination of resuscitation and failure to initiate resuscitative efforts when futility of such efforts is apparent.
8. There is a need for more research and study of infants, children, and adolescents from diverse racial,

ethnic, cultural, and socioeconomic populations to determine whether disparities in resuscitative care or outcomes exist.

9. Engagement of, partnership with, and collaboration with local communities and advocacy groups, perhaps through a community-based participatory research concept, may prove helpful in developing protocols and providing community health education programs about this subject.

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SECTION 5

Current Policies

From the American Academy of Pediatrics

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(Through January 1, 2015)

- ***Policy Statements***

*ORGANIZATIONAL PRINCIPLES TO GUIDE AND DEFINE THE CHILD HEALTH CARE SYSTEM
AND TO IMPROVE THE HEALTH OF ALL CHILDREN*

- ***Clinical Reports***

GUIDANCE FOR THE CLINICIAN IN RENDERING PEDIATRIC CARE

- ***Technical Reports***

BACKGROUND INFORMATION TO SUPPORT AMERICAN ACADEMY OF PEDIATRICS POLICY

AMERICAN ACADEMY OF PEDIATRICS

Policy Statements, Clinical Reports, Technical Reports

Current through January 1, 2015

Full text of all titles listed below is available on the *Pediatric Clinical Practice Guidelines & Policies* CD-ROM included with this manual.

2014 RECOMMENDATIONS FOR PEDIATRIC PREVENTIVE HEALTH CARE

Committee on Practice and Ambulatory Medicine and Bright Futures Periodicity Schedule Workgroup (2/14)
See full text on page 471.

AAP PRINCIPLES CONCERNING RETAIL-BASED CLINICS

Committee on Practice and Ambulatory Medicine
ABSTRACT. The American Academy of Pediatrics views retail-based clinics (RBCs) as an inappropriate source of primary care for pediatric patients, as they fragment medical care and are detrimental to the medical home concept of longitudinal and coordinated care. This statement updates the original 2006 American Academy of Pediatrics statement on RBCs, which flatly opposed these sites as appropriate for pediatric care, discussing the shift in RBC focus and comparing attributes of RBCs with those of the pediatric medical home. (2/14)
See full text on page 477.

ABUSIVE HEAD TRAUMA IN INFANTS AND CHILDREN

Cindy W. Christian, MD; Robert Block, MD; and Committee on Child Abuse and Neglect
ABSTRACT. Shaken baby syndrome is a term often used by physicians and the public to describe abusive head trauma inflicted on infants and young children. Although the term is well known and has been used for a number of decades, advances in the understanding of the mechanisms and clinical spectrum of injury associated with abusive head trauma compel us to modify our terminology to keep pace with our understanding of pathologic mechanisms. Although shaking an infant has the potential to cause neurologic injury, blunt impact or a combination of shaking and blunt impact cause injury as well. Spinal cord injury and secondary hypoxic ischemic injury can contribute to poor outcomes of victims. The use of broad medical terminology that is inclusive of all mechanisms of injury, including shaking, is required. The American Academy of Pediatrics recommends that pediatricians develop skills in the recognition of signs and symptoms of abusive head injury, including those caused by both shaking and blunt impact, consult with pediatric subspecialists when necessary, and embrace a less mechanistic term, abusive head trauma, when describing an inflicted injury to the head and its contents. (4/09, reaffirmed 3/13)

ACCESS TO OPTIMAL EMERGENCY CARE FOR CHILDREN

Committee on Pediatric Emergency Medicine
ABSTRACT. Millions of pediatric patients require some level of emergency care annually, and significant barriers limit access to appropriate services for large numbers of children. The American Academy of Pediatrics has a strong commitment to identifying barriers to access to emergency care, working to surmount these obstacles, and encouraging, through education and system changes, improved levels of emergency care available to all children. (1/07, reaffirmed 8/10, 7/14)

ACCF/AHA/AAP RECOMMENDATIONS FOR TRAINING IN PEDIATRIC CARDIOLOGY

American Academy of Pediatrics Section on Cardiology and Cardiac Surgery (joint with American College of Cardiology Foundation and American Heart Association) (12/05, reaffirmed 1/09)

ACHIEVING QUALITY HEALTH SERVICES FOR ADOLESCENTS

Committee on Adolescence
ABSTRACT. In recent years, there has been an increased national focus on assessing and improving the quality of health care. This statement provides recommendations and criteria for assessment of the quality of primary care delivered to adolescents in the United States. Consistent implementation of American Academy of Pediatrics recommendations (periodicity of visits and confidentiality issues), renewed attention to professional quality-improvement activities (access and immunizations) and public education, and modification of existing quality-measurement activities to ensure that quality is delivered are proposed as strategies that would lead to improved care for youth. (6/08, reaffirmed 3/13)

ACTIVE HEALTHY LIVING: PREVENTION OF CHILDHOOD OBESITY THROUGH INCREASED PHYSICAL ACTIVITY

Council on Sports Medicine and Fitness and Council on School Health
ABSTRACT. The current epidemic of inactivity and the associated epidemic of obesity are being driven by multiple factors (societal, technologic, industrial, commercial, financial) and must be addressed likewise on several fronts. Foremost among these are the expansion of school physical education, dissuading children from pursuing sedentary activities, providing suitable role models for physical activity, and making activity-promoting changes in the environment. This statement outlines ways that pediatric health care providers and public health officials

can encourage, monitor, and advocate for increased physical activity for children and teenagers. (5/06, reaffirmed 5/09, 8/12)

ADDITIONAL RECOMMENDATIONS FOR USE OF TETANUS TOXOID, REDUCED-CONTENT DIPHTHERIA TOXOID, AND ACELLULAR PERTUSSIS VACCINE (TDAP)

Committee on Infectious Diseases

ABSTRACT. The American Academy of Pediatrics and the Centers for Disease Control and Prevention are amending previous recommendations and making additional recommendations for the use of tetanus toxoid, reduced-content diphtheria toxoid, and acellular pertussis vaccine (Tdap). Review of the results from clinical trials and other studies has revealed no excess reactogenicity when Tdap is given within a short interval after other tetanus- or diphtheria-containing toxoid products, and accrual of postmarketing adverse-events reports reveals an excellent safety record for Tdap. Thus, the recommendation for caution regarding Tdap use within any interval after a tetanus- or diphtheria-containing toxoid product is removed. Tdap should be given when it is indicated and when no contraindication exists. In further efforts to protect people who are susceptible to pertussis, the American Academy of Pediatrics and Centers for Disease Control and Prevention recommend a single dose of Tdap for children 7 through 10 years of age who were underimmunized with diphtheria-tetanus-acellular pertussis (DTaP). Also, the age for recommendation for Tdap is extended to those aged 65 years and older who have or are likely to have contact with an infant younger than 12 months (eg, health care personnel, grandparents, and other caregivers). (9/11)

ADMISSION AND DISCHARGE GUIDELINES FOR THE PEDIATRIC PATIENT REQUIRING INTERMEDIATE CARE (CLINICAL REPORT)

*Committee on Hospital Care and Section on Critical Care
(joint with Society of Critical Care Medicine)*

ABSTRACT. During the past 3 decades, the specialty of pediatric critical care medicine has grown rapidly, leading to a number of pediatric intensive care units opening across the country. Many patients who are admitted to the hospital require a higher level of care than routine inpatient general pediatric care, yet not to the degree of intensity of pediatric critical care; therefore, an intermediate care level has been developed in institutions providing multidisciplinary subspecialty pediatric care. These patients may require frequent monitoring of vital signs and nursing interventions, but usually they do not require invasive monitoring. The admission of the pediatric intermediate care patient is guided by physiologic parameters depending on the respective organ system involved relative to an institution's resources and capacity to care for a patient in a general care environment. This report provides admission and discharge guidelines for intermediate pediatric care. Intermediate care promotes greater flexibility in patient triage and provides a cost-effective alternative to admission to a pediatric intensive care unit. This level of care may enhance the efficiency of care and make health care more affordable for patients receiving intermediate care. (5/04, reaffirmed 2/08, 1/13)

ADOLESCENT PREGNANCY: CURRENT TRENDS AND ISSUES (CLINICAL REPORT)

Jonathan D. Klein, MD, MPH, and Committee on Adolescence
ABSTRACT. The prevention of unintended adolescent pregnancy is an important goal of the American Academy of Pediatrics and our society. Although adolescent pregnancy and birth rates have been steadily decreasing, many adolescents still become pregnant. Since the last statement on adolescent pregnancy was issued by the Academy in 1998, efforts to prevent adolescent pregnancy have increased, and new observations, technologies, and prevention effectiveness data have emerged. The purpose of this clinical report is to review current trends and issues related to adolescent pregnancy, update practitioners on this topic, and review legal and policy implications of concern to pediatricians. (7/05)

ADOLESCENT PREGNANCY: CURRENT TRENDS AND ISSUES—ADDENDUM

Committee on Adolescence

INTRODUCTION. The purpose of this addendum is to update pediatricians and other professionals on recent research and data regarding adolescent sexuality, contraceptive use, and childbearing since publication of the original 2005 clinical report, "Adolescent Pregnancy: Current Trends and Issues." There has been a trend of decreasing sexual activity and teen births and pregnancies since 1991, except between the years of 2005 and 2007, when there was a 5% increase in birth rates. Currently, teen birth rates in the United States are at a record low secondary to increased use of contraception at first intercourse and use of dual methods of condoms and hormonal contraception among sexually active teenagers. Despite these data, the United States continues to lead other industrialized countries in having unacceptably high rates of adolescent pregnancy, with over 700,000 pregnancies per year, the direct health consequence of unprotected intercourse. Importantly, the 2006–2010 National Survey of Family Growth (NSFG) revealed that less than one-third of 15- to 19-year-old female subjects consistently used contraceptive methods at last intercourse. (4/14)

See full text on page 483.

ADOLESCENTS AND HIV INFECTION: THE PEDIATRICIAN'S ROLE IN PROMOTING ROUTINE TESTING

Committee on Pediatric AIDS

ABSTRACT. Pediatricians can play a key role in preventing and controlling HIV infection by promoting risk-reduction counseling and offering routine HIV testing to adolescent and young adult patients. Most sexually active youth do not feel that they are at risk of contracting HIV and have never been tested. Obtaining a sexual history and creating an atmosphere that promotes nonjudgmental risk counseling is a key component of the adolescent visit. In light of increasing numbers of people with HIV/AIDS and missed opportunities for HIV testing, the Centers for Disease Control and Prevention recommends universal and routine HIV testing for all patients seen in health care settings who are 13 to 64 years of age. There are advances in diagnostics and treatment that help support

this recommendation. This policy statement reviews the epidemiologic data and recommends that routine screening be offered to all adolescents at least once by 16 to 18 years of age in health care settings when the prevalence of HIV in the patient population is more than 0.1%. In areas of lower community HIV prevalence, routine HIV testing is encouraged for all sexually active adolescents and those with other risk factors for HIV. This statement addresses many of the real and perceived barriers that pediatricians face in promoting routine HIV testing for their patients. (10/11)

ADOLESCENTS AND HUMAN IMMUNODEFICIENCY VIRUS INFECTION: THE ROLE OF THE PEDIATRICIAN IN PREVENTION AND INTERVENTION

Committee on Pediatric AIDS and Committee on Adolescence

ABSTRACT. Half of all new human immunodeficiency virus (HIV) infections in the United States occur among young people between the ages of 13 and 24. Sexual transmission accounts for most cases of HIV during adolescence. Pediatricians can play an important role in educating adolescents about HIV prevention, transmission, and testing, with an emphasis on risk reduction, and in advocating for the special needs of adolescents for access to information about HIV. (1/01, reaffirmed 10/03, 1/05)

THE ADOLESCENT'S RIGHT TO CONFIDENTIAL CARE WHEN CONSIDERING ABORTION

Committee on Adolescence

ABSTRACT. In this statement, the American Academy of Pediatrics (AAP) reaffirms its position that the rights of adolescents to confidential care when considering abortion should be protected. The AAP supports the recommendations presented in the report on mandatory parental consent to abortion by the Council on Ethical and Judicial Affairs of the American Medical Association. Adolescents should be strongly encouraged to involve their parents and other trusted adults in decisions regarding pregnancy termination, and the majority of them voluntarily do so. Legislation mandating parental involvement does not achieve the intended benefit of promoting family communication, but it does increase the risk of harm to the adolescent by delaying access to appropriate medical care. The statement presents a summary of pertinent current information related to the benefits and risks of legislation requiring mandatory parental involvement in an adolescent's decision to obtain an abortion. The AAP acknowledges and respects the diversity of beliefs about abortion and affirms the value of voluntary parental involvement in decision making by adolescents. (5/96, reaffirmed 5/99, 11/02)

ADVANCED PRACTICE IN NEONATAL NURSING

Committee on Fetus and Newborn

ABSTRACT. The participation of advanced practice registered nurses in neonatal care continues to be accepted and supported by the American Academy of Pediatrics. Recognized categories of advanced practice neonatal nursing are the neonatal clinical nurse specialist and the neonatal nurse practitioner. (5/09, reaffirmed 1/14)

AGE LIMITS OF PEDIATRICS

Child and Adolescent Health Action Group (5/88, reaffirmed 9/92, 1/97, 3/02, 1/06, 10/11)

AGE TERMINOLOGY DURING THE PERINATAL PERIOD

Committee on Fetus and Newborn

ABSTRACT. Consistent definitions to describe the length of gestation and age in neonates are needed to compare neurodevelopmental, medical, and growth outcomes. The purposes of this policy statement are to review conventional definitions of age during the perinatal period and to recommend use of standard terminology including gestational age, postmenstrual age, chronological age, corrected age, adjusted age, and estimated date of delivery. (11/04, reaffirmed 10/07, 11/08, 1/09, 7/14)

ALCOHOL USE BY YOUTH AND ADOLESCENTS: A PEDIATRIC CONCERN

Committee on Substance Abuse

ABSTRACT. Alcohol use continues to be a major problem from preadolescence through young adulthood in the United States. Results of recent neuroscience research have substantiated the deleterious effects of alcohol on adolescent brain development and added even more evidence to support the call to prevent and reduce underaged drinking. Pediatricians should be knowledgeable about substance abuse to be able to recognize risk factors for alcohol and other substance abuse among youth, screen for use, provide appropriate brief interventions, and refer to treatment. The integration of alcohol use prevention programs in the community and our educational system from elementary school through college should be promoted by pediatricians and the health care community. Promotion of media responsibility to connect alcohol consumption with realistic consequences should be supported by pediatricians. Additional research into the prevention, screening and identification, brief intervention, and management and treatment of alcohol and other substance use by adolescents continues to be needed to improve evidence-based practices. (4/10)

ALLERGY TESTING IN CHILDHOOD: USING ALLERGEN-SPECIFIC IGE TESTS (CLINICAL REPORT)

Scott H. Sicherer, MD; Robert A. Wood, MD; and Section on Allergy and Immunology

ABSTRACT. A variety of triggers can induce common pediatric allergic diseases which include asthma, allergic rhinitis, atopic dermatitis, food allergy, and anaphylaxis. Allergy testing serves to confirm an allergic trigger suspected on the basis of history. Tests for allergen-specific immunoglobulin E (IgE) are performed by in vitro assays or skin tests. The tests are excellent for identifying a sensitized state in which allergen-specific IgE is present, and may identify triggers to be eliminated and help guide immunotherapy treatment. However, a positive test result does not always equate with clinical allergy. Newer enzymatic assays based on anti-IgE antibodies have supplanted the radioallergosorbent test (RAST). This clinical report focuses on allergen-specific IgE testing, emphasizing that the medical history and knowledge of disease characteristics are crucial for rational test selection and interpretation. (12/11)

ALL-TERRAIN VEHICLE INJURY PREVENTION: TWO-, THREE-, AND FOUR-WHEELED UNLICENSED MOTOR VEHICLES

Committee on Injury and Poison Prevention

ABSTRACT. Since 1987, the American Academy of Pediatrics (AAP) has had a policy about the use of motorized cycles and all-terrain vehicles (ATVs) by children. The purpose of this policy statement is to update and strengthen previous policy. This statement describes the various kinds of motorized cycles and ATVs and outlines the epidemiologic characteristics of deaths and injuries related to their use by children in light of the 1987 consent decrees entered into by the US Consumer Product Safety Commission and the manufacturers of ATVs. Recommendations are made for public, patient, and parent education by pediatricians; equipment modifications; the use of safety equipment; and the development and improvement of safer off-road trails and responsive emergency medical systems. In addition, the AAP strengthens its recommendation for passage of legislation in all states prohibiting the use of 2- and 4-wheeled off-road vehicles by children younger than 16 years, as well as a ban on the sale of new and used 3-wheeled ATVs, with a recall of all used 3-wheeled ATVs. (6/00, reaffirmed 5/04, 1/07, 5/13)

AMBIENT AIR POLLUTION: HEALTH HAZARDS TO CHILDREN

Committee on Environmental Health

ABSTRACT. Ambient (outdoor) air pollution is now recognized as an important problem, both nationally and worldwide. Our scientific understanding of the spectrum of health effects of air pollution has increased, and numerous studies are finding important health effects from air pollution at levels once considered safe. Children and infants are among the most susceptible to many of the air pollutants. In addition to associations between air pollution and respiratory symptoms, asthma exacerbations, and asthma hospitalizations, recent studies have found links between air pollution and preterm birth, infant mortality, deficits in lung growth, and possibly, development of asthma. This policy statement summarizes the recent literature linking ambient air pollution to adverse health outcomes in children and includes a perspective on the current regulatory process. The statement provides advice to pediatricians on how to integrate issues regarding air quality and health into patient education and children's environmental health advocacy and concludes with recommendations to the government on promotion of effective air-pollution policies to ensure protection of children's health. (12/04, reaffirmed 4/09)

ANTENATAL COUNSELING REGARDING RESUSCITATION AT AN EXTREMELY LOW GESTATIONAL AGE (CLINICAL REPORT)

Daniel G. Batton, MD, and Committee on Fetus and Newborn

ABSTRACT. The anticipated delivery of an extremely low gestational age infant raises difficult questions for all involved, including whether to initiate resuscitation after delivery. Each institution caring for women at risk of delivering extremely preterm infants should provide comprehensive and consistent guidelines for antenatal counseling. Parents should be provided the most accurate

prognosis possible on the basis of all the factors known to affect outcome for a particular case. Although it is not feasible to have specific criteria for when the initiation of resuscitation should or should not be offered, the following general guidelines are suggested. If the physicians involved believe there is no chance for survival, resuscitation is not indicated and should not be initiated. When a good outcome is considered very unlikely, the parents should be given the choice of whether resuscitation should be initiated, and clinicians should respect their preference. Finally, if a good outcome is considered reasonably likely, clinicians should initiate resuscitation and, together with the parents, continually reevaluate whether intensive care should be continued. Whenever resuscitation is considered an option, a qualified individual, preferably a neonatologist, should be involved and should be present in the delivery room to manage this complex situation. Comfort care should be provided for all infants for whom resuscitation is not initiated or is not successful. (6/09)

ANTERIOR CRUCIATE LIGAMENT INJURIES: DIAGNOSIS, TREATMENT, AND PREVENTION (CLINICAL REPORT)

Cynthia R. LaBella, MD, FAAP; William Hennrikus, MD, FAAP; Timothy E. Hewett, PhD, FACSM; Council on

Sports Medicine and Fitness; and Section on Orthopaedics
ABSTRACT. The number of anterior cruciate ligament (ACL) injuries reported in athletes younger than 18 years has increased over the past 2 decades. Reasons for the increasing ACL injury rate include the growing number of children and adolescents participating in organized sports, intensive sports training at an earlier age, and greater rate of diagnosis because of increased awareness and greater use of advanced medical imaging. ACL injury rates are low in young children and increase sharply during puberty, especially for girls, who have higher rates of noncontact ACL injuries than boys do in similar sports. Intrinsic risk factors for ACL injury include higher BMI, subtalar joint overpronation, generalized ligamentous laxity, and decreased neuromuscular control of knee motion. ACL injuries often require surgery and/or many months of rehabilitation and substantial time lost from school and sports participation. Unfortunately, regardless of treatment, athletes with ACL injuries are up to 10 times more likely to develop degenerative arthritis of the knee. Safe and effective surgical techniques for children and adolescents continue to evolve. Neuromuscular training can reduce risk of ACL injury in adolescent girls. This report outlines the current state of knowledge on epidemiology, diagnosis, treatment, and prevention of ACL injuries in children and adolescents. (4/14)

See full text on page 489.

THE APGAR SCORE

Committee on Fetus and Newborn (joint with American College of Obstetricians and Gynecologists)

ABSTRACT. The Apgar score provides a convenient shorthand for reporting the status of the newborn infant and the response to resuscitation. The Apgar score has been used inappropriately to predict specific neurologic outcome in the term infant. There are no consistent data on the significance of the Apgar score in preterm infants.

The Apgar score has limitations, and it is inappropriate to use it alone to establish the diagnosis of asphyxia. An Apgar score assigned during resuscitation is not equivalent to a score assigned to a spontaneously breathing infant. An expanded Apgar score reporting form will account for concurrent resuscitative interventions and provide information to improve systems of perinatal and neonatal care. (4/06, reaffirmed 1/09)

APPLICATION OF THE RESOURCE-BASED RELATIVE VALUE SCALE SYSTEM TO PEDIATRICS

Committee on Coding and Nomenclature

ABSTRACT. The majority of public and private payers in the United States currently use the Medicare Resource-Based Relative Value Scale as the basis for physician payment. Many large group and academic practices have adopted this objective system of physician work to benchmark physician productivity, including using it, wholly or in part, to determine compensation. The Resource-Based Relative Value Scale survey instrument, used to value physician services, was designed primarily for procedural services, leading to current concerns that American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) surveys may undervalue nonprocedural evaluation and management services. The American Academy of Pediatrics is represented on the RUC, the committee charged with maintaining accurate physician work values across specialties and age groups. The Academy, working closely with other primary care and subspecialty societies, actively pursues a balanced RUC membership and a survey instrument that will ensure appropriate work relative value unit assignments, thereby allowing pediatricians to receive appropriate payment for their services relative to other services. (5/14)

See full text on page 505.

ASSESSMENT AND MANAGEMENT OF INGUINAL HERNIA IN INFANTS (CLINICAL REPORT)

Kasper S. Wang, MD; Committee on Fetus and Newborn; and Section on Surgery

ABSTRACT. Inguinal hernia repair in infants is a routine surgical procedure. However, numerous issues, including timing of the repair, the need to explore the contralateral groin, use of laparoscopy, and anesthetic approach, remain unsettled. Given the lack of compelling data, consideration should be given to large, prospective, randomized controlled trials to determine best practices for the management of inguinal hernias in infants. (9/12)

ATHLETIC PARTICIPATION BY CHILDREN AND ADOLESCENTS WHO HAVE SYSTEMIC HYPERTENSION

Rebecca A. Demorest, MD; Reginald L. Washington, MD; and Council on Sports Medicine and Fitness

ABSTRACT. Children and adolescents who have hypertension may be at risk for complications when exercise causes their blood pressure to rise even higher. The purpose of this statement is to update recommendations concerning the athletic participation of individuals with hypertension, including special populations such as those with spinal cord injuries or obesity, by using the guidelines from "The 36th Bethesda Conference: Eligibility Recommendations for Competitive Athletes

with Cardiovascular Abnormalities"; "The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents"; and "The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure." (5/10, reaffirmed 5/13)

ATOPIC DERMATITIS: SKIN-DIRECTED MANAGEMENT (CLINICAL REPORT)

Megha M. Tollefson, MD; Anna L. Bruckner, MD, FAAP; Section on Dermatology

ABSTRACT. Atopic dermatitis is a common inflammatory skin condition characterized by relapsing eczematous lesions in a typical distribution. It can be frustrating for pediatric patients, parents, and health care providers alike. The pediatrician will treat the majority of children with atopic dermatitis as many patients will not have access to a pediatric medical subspecialist, such as a pediatric dermatologist or pediatric allergist. This report provides up-to-date information regarding the disease and its impact, pathogenesis, treatment options, and potential complications. The goal of this report is to assist pediatricians with accurate and useful information that will improve the care of patients with atopic dermatitis. (11/14)

See full text on page 513.

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER AND SUBSTANCE ABUSE (CLINICAL REPORT)

Elizabeth Harstad, MD, MPH, FAAP; Sharon Levy, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Attention-deficit/hyperactivity disorder (ADHD) and substance use disorders are inextricably intertwined. Children with ADHD are more likely than peers to develop substance use disorders. Treatment with stimulants may reduce the risk of substance use disorders, but stimulants are a class of medication with significant abuse and diversion potential. The objectives of this clinical report were to present practical strategies for reducing the risk of substance use disorders in patients with ADHD and suggestions for safe stimulant prescribing. (6/14)

See full text on page 525.

AUDITORY INTEGRATION TRAINING AND FACILITATED COMMUNICATION FOR AUTISM

Committee on Children With Disabilities

ABSTRACT. This statement reviews the basis for two new therapies for autism—auditory integration training and facilitative communication. Both therapies seek to improve communication skills. Currently available information does not support the claims of proponents that these treatments are efficacious. Their use does not appear warranted at this time, except within research protocols. (8/98, reaffirmed 5/02, 1/06, 12/09)

BASEBALL AND SOFTBALL

Council on Sports Medicine and Fitness

ABSTRACT. Baseball and softball are among the most popular and safest sports in which children and adolescents participate. Nevertheless, traumatic and overuse injuries occur regularly, including occasional catastrophic injury and even death. Safety of the athlete is a constant focus of attention among those responsible for modifying rules. Understanding the stresses placed on the arm, espe-

cially while pitching, led to the institution of rules controlling the quantity of pitches thrown in youth baseball and established rest periods between pitching assignments. Similarly, field maintenance and awareness of environmental conditions as well as equipment maintenance and creative prevention strategies are critically important in minimizing the risk of injury. This statement serves as a basis for encouraging safe participation in baseball and softball. This statement has been endorsed by the Canadian Paediatric Society. (2/12)

BICYCLE HELMETS

Committee on Injury and Poison Prevention

ABSTRACT. Bicycling remains one of the most popular recreational sports among children in America and is the leading cause of recreational sports injuries treated in emergency departments. An estimated 23 000 children younger than 21 years sustained head injuries (excluding the face) while bicycling in 1998. The bicycle helmet is a very effective device that can prevent the occurrence of up to 88% of serious brain injuries. Despite this, most children do not wear a helmet each time they ride a bicycle, and adolescents are particularly resistant to helmet use. Recently, a group of national experts and government agencies renewed the call for all bicyclists to wear helmets. This policy statement describes the role of the pediatrician in helping attain universal helmet use among children and teens for each bicycle ride. (10/01, reaffirmed 1/05, 2/08, 11/11)

BONE DENSITOMETRY IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Laura K. Bachrach, MD; Irene N. Sills, MD; and Section on Endocrinology

ABSTRACT. Concern for bone fragility in children and adolescents has led to increased interest in bone densitometry. Pediatric patients with genetic and acquired chronic diseases, immobility, and inadequate nutrition may fail to achieve the expected gains in bone size, mass, and strength, which leaves them vulnerable to fracture. In older adults, bone densitometry has been shown to predict fracture risk and reflect response to therapy. The role of densitometry in the management of children at risk of bone fragility is less certain. This clinical report summarizes the current knowledge about bone densitometry in the pediatric population, including indications for its use, interpretation of results, and its risks and costs. This report emphasizes consensus statements generated at the 2007 Pediatric Position Development Conference of the International Society of Clinical Densitometry by an international panel of bone experts. Some of these recommendations are evidence-based, and others reflect expert opinion, because the available data are inadequate. The statements from this and other expert panels have provided general guidance to the pediatrician, but decisions about ordering and interpreting bone densitometry still require clinical judgment. Ongoing studies will help to better define the indications and best methods for assessing bone strength in children and the clinical factors that contribute to fracture risk. (12/10)

BOXING PARTICIPATION BY CHILDREN AND ADOLESCENTS

Council on Sports Medicine and Fitness (joint with Canadian Paediatric Society Healthy Active Living and Sports Medicine Committee)

ABSTRACT. Thousands of boys and girls younger than 19 years participate in boxing in North America. Although boxing provides benefits for participants, including exercise, self-discipline, and self-confidence, the sport of boxing encourages and rewards deliberate blows to the head and face. Participants in boxing are at risk of head, face, and neck injuries, including chronic and even fatal neurologic injuries. Concussions are one of the most common injuries that occur with boxing. Because of the risk of head and facial injuries, the American Academy of Pediatrics and the Canadian Paediatric Society oppose boxing as a sport for children and adolescents. These organizations recommend that physicians vigorously oppose boxing in youth and encourage patients to participate in alternative sports in which intentional head blows are not central to the sport. (8/11)

BREASTFEEDING AND THE USE OF HUMAN MILK

Section on Breastfeeding

ABSTRACT. Breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short- and long-term medical and neurodevelopmental advantages of breastfeeding, infant nutrition should be considered a public health issue and not only a lifestyle choice. The American Academy of Pediatrics reaffirms its recommendation of exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare. Infant growth should be monitored with the World Health Organization (WHO) Growth Curve Standards to avoid mislabeling infants as underweight or failing to thrive. Hospital routines to encourage and support the initiation and sustaining of exclusive breastfeeding should be based on the American Academy of Pediatrics-endorsed WHO/UNICEF "Ten Steps to Successful Breastfeeding." National strategies supported by the US Surgeon General's Call to Action, the Centers for Disease Control and Prevention, and The Joint Commission are involved to facilitate breastfeeding practices in US hospitals and communities. Pediatricians play a critical role in their practices and communities as advocates of breastfeeding and thus should be knowledgeable about the health risks of not breastfeeding, the economic benefits to society of breastfeeding, and the techniques for managing and supporting the breastfeeding dyad. The "Business Case for Breastfeeding" details how mothers can maintain lactation in the workplace and the benefits to employers who facilitate this practice. (2/12)

THE BUILT ENVIRONMENT: DESIGNING COMMUNITIES TO PROMOTE PHYSICAL ACTIVITY IN CHILDREN

Committee on Environmental Health

ABSTRACT. An estimated 32% of American children are overweight, and physical inactivity contributes to this high prevalence of overweight. This policy statement highlights how the built environment of a community affects children's opportunities for physical activity. Neighborhoods and communities can provide opportunities for recreational physical activity with parks and open spaces, and policies must support this capacity. Children can engage in physical activity as a part of their daily lives, such as on their travel to school. Factors such as school location have played a significant role in the decreased rates of walking to school, and changes in policy may help to increase the number of children who are able to walk to school. Environment modification that addresses risks associated with automobile traffic is likely to be conducive to more walking and biking among children. Actions that reduce parental perception and fear of crime may promote outdoor physical activity. Policies that promote more active lifestyles among children and adolescents will enable them to achieve the recommended 60 minutes of daily physical activity. By working with community partners, pediatricians can participate in establishing communities designed for activity and health. (5/09, reaffirmed 1/13)

CALCIUM AND VITAMIN D REQUIREMENTS OF ENTERALLY FED PRETERM INFANTS (CLINICAL REPORT)

Steven A. Abrams, MD, and Committee on Nutrition

ABSTRACT. Bone health is a critical concern in managing preterm infants. Key nutrients of importance are calcium, vitamin D, and phosphorus. Although human milk is critical for the health of preterm infants, it is low in these nutrients relative to the needs of the infants during growth. Strategies should be in place to fortify human milk for preterm infants with birth weight <1800 to 2000 g and to ensure adequate mineral intake during hospitalization and after hospital discharge. Biochemical monitoring of very low birth weight infants should be performed during their hospitalization. Vitamin D should be provided at 200 to 400 IU/day both during hospitalization and after discharge from the hospital. Infants with radiologic evidence of rickets should have efforts made to maximize calcium and phosphorus intake by using available commercial products and, if needed, direct supplementation with these minerals. (4/13)

CARDIOVASCULAR HEALTH SUPERVISION FOR INDIVIDUALS AFFECTED BY DUCHENNE OR BECKER MUSCULAR DYSTROPHY (CLINICAL REPORT)

Section on Cardiology and Cardiac Surgery

ABSTRACT. Duchenne muscular dystrophy is the most common and severe form of the childhood muscular dystrophies. The disease is typically diagnosed between 3 and 7 years of age and follows a predictable clinical course marked by progressive skeletal muscle weakness with loss of ambulation by 12 years of age. Death occurs in early adulthood secondary to respiratory or cardiac failure. Becker muscular dystrophy is less common and has

a milder clinical course but also results in respiratory and cardiac failure. The natural history of the cardiomyopathy in these diseases has not been well established. As a result, patients traditionally present for cardiac evaluation only after clinical symptoms become evident. The purpose of this policy statement is to provide recommendations for optimal cardiovascular evaluation to health care specialists caring for individuals in whom the diagnosis of Duchenne or Becker muscular dystrophy has been confirmed. (12/05, reaffirmed 1/09)

CARDIOVASCULAR MONITORING AND STIMULANT DRUGS FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

James M. Perrin, MD; Richard A. Friedman, MD; Timothy K. Knillans, MD; Black Box Working Group; and Section on Cardiology and Cardiac Surgery

ABSTRACT. A recent American Heart Association (AHA) statement recommended electrocardiograms (ECGs) routinely for children before they start medications to treat attention-deficit/hyperactivity disorder (ADHD). The AHA statement reflected the thoughtful work of a group committed to improving the health of children with heart disease. However, the recommendation to obtain an ECG before starting medications for treating ADHD contradicts the carefully considered and evidence-based recommendations of the American Academy of Child and Adolescent Psychiatry and the American Academy of Pediatrics (AAP). These organizations have concluded that sudden cardiac death (SCD) in persons taking medications for ADHD is a very rare event, occurring at rates no higher than those in the general population of children and adolescents. Both of these groups also noted the lack of any evidence that the routine use of ECG screening before beginning medication for ADHD treatment would prevent sudden death. The AHA statement pointed out the importance of detecting silent but clinically important cardiac conditions in children and adolescents, which is a goal that the AAP shares. The primary purpose of the AHA statement is to prevent cases of SCD that may be related to stimulant medications. The recommendations of the AAP and the rationale for these recommendations are the subject of this statement. (8/08)

CARE COORDINATION IN THE MEDICAL HOME: INTEGRATING HEALTH AND RELATED SYSTEMS OF CARE FOR CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Council on Children With Disabilities

ABSTRACT. Care coordination is a process that facilitates the linkage of children and their families with appropriate services and resources in a coordinated effort to achieve good health. Care coordination for children with special health care needs often is complicated because there is no single point of entry into the multiple systems of care, and complex criteria frequently determine the availability of funding and services among public and private payers. Economic and sociocultural barriers to coordination of care exist and affect families and health care professionals. In their important role of providing a medical home for all children, primary care physicians have a vital role in the process of care coordination, in concert with the family. (11/05)

CARE OF ADOLESCENT PARENTS AND THEIR CHILDREN (CLINICAL REPORT)

Jorge L. Pinzon, MD; Veronnie F. Jones, MD; Committee on Adolescence; and Committee on Early Childhood

ABSTRACT. Teen pregnancy and parenting remain an important public health issue in the United States and the world, and many children live with their adolescent parents alone or as part of an extended family. A significant proportion of teen parents reside with their family of origin, significantly affecting the multigenerational family structure. Repeated births to teen parents are also common. This clinical report updates a previous policy statement on care of the adolescent parent and their children and addresses medical and psychosocial risks specific to this population. Challenges unique to teen parents and their children are reviewed, along with suggestions for the pediatrician on models for intervention and care. (11/12)

CARE OF THE ADOLESCENT SEXUAL ASSAULT VICTIM (CLINICAL REPORT)

Miriam Kaufman, MD, and Committee on Adolescence

ABSTRACT. Sexual assault is a broad-based term that encompasses a wide range of sexual victimizations including rape. Since the American Academy of Pediatrics published its last policy statement on sexual assault in 2001, additional information and data have emerged about sexual assault and rape in adolescents and the treatment and management of the adolescent who has been a victim of sexual assault. This report provides new information to update physicians and focuses on assessment and care of sexual assault victims in the adolescent population. (8/08)

CAREGIVER-FABRICATED ILLNESS IN A CHILD: A MANIFESTATION OF CHILD MALTREATMENT (CLINICAL REPORT)

Emalee G. Flaherty, MD; Harriet L. MacMillan, MD; and Committee on Child Abuse and Neglect

ABSTRACT. Caregiver-fabricated illness in a child is a form of child maltreatment caused by a caregiver who falsifies and/or induces a child's illness, leading to unnecessary and potentially harmful medical investigations and/or treatment. This condition can result in significant morbidity and mortality. Although caregiver-fabricated illness in a child has been widely known as Munchausen syndrome by proxy, there is ongoing discussion about alternative names, including pediatric condition falsification, factitious disorder (illness) by proxy, child abuse in the medical setting, and medical child abuse. Because it is a relatively uncommon form of maltreatment, pediatricians need to have a high index of suspicion when faced with a persistent or recurrent illness that cannot be explained and that results in multiple medical procedures or when there are discrepancies between the history, physical examination, and health of a child. This report updates the previous clinical report "Beyond Munchausen Syndrome by Proxy: Identification and Treatment of Child Abuse in the Medical Setting." The authors discuss the need to agree on appropriate terminology, provide an update on published reports of new manifestations of fabricated medical conditions, and discuss approaches to assessment, diagnosis, and management, including how best to protect the child from further harm. (8/13)

THE CHANGING CONCEPT OF SUDDEN INFANT DEATH SYNDROME: DIAGNOSTIC CODING SHIFTS, CONTROVERSIES REGARDING THE SLEEPING ENVIRONMENT, AND NEW VARIABLES TO CONSIDER IN REDUCING RISK

Task Force on Sudden Infant Death Syndrome

ABSTRACT. There has been a major decrease in the incidence of sudden infant death syndrome (SIDS) since the American Academy of Pediatrics (AAP) released its recommendation in 1992 that infants be placed down for sleep in a nonprone position. Although the SIDS rate continues to fall, some of the recent decrease of the last several years may be a result of coding shifts to other causes of unexpected infant deaths. Since the AAP published its last statement on SIDS in 2000, several issues have become relevant, including the significant risk of side sleeping position; the AAP no longer recognizes side sleeping as a reasonable alternative to fully supine sleeping. The AAP also stresses the need to avoid redundant soft bedding and soft objects in the infant's sleeping environment, the hazards of adults sleeping with an infant in the same bed, the SIDS risk reduction associated with having infants sleep in the same room as adults and with using pacifiers at the time of sleep, the importance of educating secondary caregivers and neonatology practitioners on the importance of "back to sleep," and strategies to reduce the incidence of positional plagiocephaly associated with supine positioning. This statement reviews the evidence associated with these and other SIDS-related issues and proposes new recommendations for further reducing SIDS risk. (11/05, reaffirmed 5/08)

CHEERLEADING INJURIES: EPIDEMIOLOGY AND RECOMMENDATIONS FOR PREVENTION

Council on Sports Medicine and Fitness

ABSTRACT. Over the last 30 years, cheerleading has increased dramatically in popularity and has evolved from leading the crowd in cheers at sporting events into a competitive, year-round sport involving complex acrobatic stunts and tumbling. Consequently, cheerleading injuries have steadily increased over the years in both number and severity. Sprains and strains to the lower extremities are the most common injuries. Although the overall injury rate remains relatively low, cheerleading has accounted for approximately 66% of all catastrophic injuries in high school girl athletes over the past 25 years. Risk factors for injuries in cheerleading include higher BMI, previous injury, cheering on harder surfaces, performing stunts, and supervision by a coach with low level of training and experience. This policy statement describes the epidemiology of cheerleading injuries and provides recommendations for injury prevention. (10/12)

CHEMICAL-BIOLOGICAL TERRORISM AND ITS IMPACT ON CHILDREN

Committee on Environmental Health and Committee on Infectious Diseases

ABSTRACT. Children remain potential victims of chemical or biological terrorism. In recent years, children have even been specific targets of terrorist acts. Consequently, it is necessary to address the needs that children would face after a terrorist incident. A broad range of public health initiatives have occurred since September 11, 2001.

Although the needs of children have been addressed in many of them, in many cases, these initiatives have been inadequate in ensuring the protection of children. In addition, public health and health care system preparedness for terrorism has been broadened to the so-called all-hazards approach, in which response plans for terrorism are blended with plans for a public health or health care system response to unintentional disasters (eg, natural events such as earthquakes or pandemic flu or manmade catastrophes such as a hazardous-materials spill). In response to new principles and programs that have appeared over the last 5 years, this policy statement provides an update of the 2000 policy statement. The roles of both the pediatrician and public health agencies continue to be emphasized; only a coordinated effort by pediatricians and public health can ensure that the needs of children, including emergency protocols in schools or child care centers, decontamination protocols, and mental health interventions, will be successful. (9/06, reaffirmed 1/11)

CHEMICAL-MANAGEMENT POLICY: PRIORITIZING CHILDREN'S HEALTH

Council on Environmental Health

ABSTRACT. The American Academy of Pediatrics recommends that chemical-management policy in the United States be revised to protect children and pregnant women and to better protect other populations. The Toxic Substance Control Act (TSCA) was passed in 1976. It is widely recognized to have been ineffective in protecting children, pregnant women, and the general population from hazardous chemicals in the marketplace. It does not take into account the special vulnerabilities of children in attempting to protect the population from chemical hazards. Its processes are so cumbersome that in its more than 30 years of existence, the TSCA has been used to regulate only 5 chemicals or chemical classes of the tens of thousands of chemicals that are in commerce. Under the TSCA, chemical companies have no responsibility to perform premarket testing or postmarket follow-up of the products that they produce; in fact, the TSCA contains disincentives for the companies to produce such data. Voluntary programs have been inadequate in resolving problems. Therefore, chemical-management policy needs to be rewritten in the United States. Manufacturers must be responsible for developing information about chemicals before marketing. The US Environmental Protection Agency must have the authority to demand additional safety data about a chemical and to limit or stop the marketing of a chemical when there is a high degree of suspicion that the chemical might be harmful to children, pregnant women, or other populations. (4/11)

CHILD ABUSE, CONFIDENTIALITY, AND THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Committee on Child Abuse and Neglect

ABSTRACT. The federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 has significantly affected clinical practice, particularly with regard to how patient information is shared. HIPAA addresses the security and privacy of patient health data, ensuring that information is released appropriately with patient or guardian

consent and knowledge. However, when child abuse or neglect is suspected in a clinical setting, the physician may determine that release of information without consent is necessary to ensure the health and safety of the child. This policy statement provides an overview of HIPAA regulations with regard to the role of the pediatrician in releasing or reviewing patient health information when the patient is a child who is a suspected victim of abuse or neglect. This statement is based on the most current regulations provided by the US Department of Health and Human Services and is subject to future changes and clarifications as updates are provided. (12/09, reaffirmed 1/14)

CHILD FATALITY REVIEW

Cindy W. Christian, MD; Robert D. Sege, MD, PhD;

Committee on Child Abuse and Neglect; Committee on Injury, Violence, and Poison Prevention; and Council on Community Pediatrics

ABSTRACT. Injury remains the leading cause of pediatric mortality and requires public health approaches to reduce preventable deaths. Child fatality review teams, first established to review suspicious child deaths involving abuse or neglect, have expanded toward a public health model of prevention of child fatality through systematic review of child deaths from birth through adolescence. Approximately half of all states report reviewing child deaths from all causes, and the process of fatality review has identified effective local and state prevention strategies for reducing child deaths. This expanded approach can be a powerful tool in understanding the epidemiology and preventability of child death locally, regionally, and nationally; improving accuracy of vital statistics data; and identifying public health and legislative strategies for reducing preventable child fatalities. The American Academy of Pediatrics supports the development of federal and state legislation to enhance the child fatality review process and recommends that pediatricians become involved in local and state child death reviews. (8/10, reaffirmed 5/14)

CHILD LIFE SERVICES

Committee on Hospital Care and Child Life Council

ABSTRACT. Child life programs are an important component of pediatric hospital-based care to address the psychosocial concerns that accompany hospitalization and other health care experiences. Child life specialists focus on the optimal development and well-being of infants, children, adolescents, and young adults while promoting coping skills and minimizing the adverse effects of hospitalization, health care, and/or other potentially stressful experiences. Using therapeutic play, expressive modalities, and psychological preparation as primary tools, in collaboration with the entire health care team and family, child life interventions facilitate coping and adjustment at times and under circumstances that might otherwise prove overwhelming for the child. Play and developmentally appropriate communication are used to: (1) promote optimal development; (2) educate children and families about health conditions; (3) prepare children and families for medical events or procedures; (4) plan and rehearse useful coping and pain management strategies; (5) help children work through feelings about past or impending

experiences; and (6) establish therapeutic relationships with patients, siblings, and parents to support family involvement in each child's care. (4/14)

See full text on page 537.

CHILD PASSENGER SAFETY

*Committee on Injury, Violence,
and Poison Prevention*



ABSTRACT. Child passenger safety has dramatically evolved over the past decade; however, motor vehicle crashes continue to be the leading cause of death of children 4 years and older. This policy statement provides 4 evidence-based recommendations for best practices in the choice of a child restraint system to optimize safety in passenger vehicles for children from birth through adolescence: (1) rear-facing car safety seats for most infants up to 2 years of age; (2) forward-facing car safety seats for most children through 4 years of age; (3) belt-positioning booster seats for most children through 8 years of age; and (4) lap-and-shoulder seat belts for all who have outgrown booster seats. In addition, a fifth evidence-based recommendation is for all children younger than 13 years to ride in the rear seats of vehicles. It is important to note that every transition is associated with some decrease in protection; therefore, parents should be encouraged to delay these transitions for as long as possible. These recommendations are presented in the form of an algorithm that is intended to facilitate implementation of the recommendations by pediatricians to their patients and families and should cover most situations that pediatricians will encounter in practice. The American Academy of Pediatrics urges all pediatricians to know and promote these recommendations as part of child passenger safety anticipatory guidance at every health-supervision visit. (3/11)

CHILD PASSENGER SAFETY (TECHNICAL REPORT)

Dennis R. Durbin, MD, MSCE,



and Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Despite significant reductions in the number of children killed in motor vehicle crashes over the past decade, crashes continue to be the leading cause of death for children 4 years and older. Therefore, the American Academy of Pediatrics continues to recommend inclusion of child passenger safety anticipatory guidance at every health-supervision visit. This technical report provides a summary of the evidence in support of 5 recommendations for best practices to optimize safety in passenger vehicles for children from birth through adolescence that all pediatricians should know and promote in their routine practice. These recommendations are presented in the revised policy statement on child passenger safety in the form of an algorithm that is intended to facilitate their implementation by pediatricians with their patients and families. The algorithm is designed to cover the majority of situations that pediatricians will encounter in practice. In addition, a summary of evidence on a number of additional issues that affect the safety of children in motor vehicles, including the proper use and installation of child restraints, exposure to air bags, travel in pickup trucks,

children left in or around vehicles, and the importance of restraint laws, is provided. Finally, this technical report provides pediatricians with a number of resources for additional information to use when providing anticipatory guidance to families. (3/11)

CHILDREN, ADOLESCENTS, AND ADVERTISING

Committee on Communications

ABSTRACT. Advertising is a pervasive influence on children and adolescents. Young people view more than 40 000 ads per year on television alone and increasingly are being exposed to advertising on the Internet, in magazines, and in schools. This exposure may contribute significantly to childhood and adolescent obesity, poor nutrition, and cigarette and alcohol use. Media education has been shown to be effective in mitigating some of the negative effects of advertising on children and adolescents. (12/06, reaffirmed 3/10)

CHILDREN, ADOLESCENTS, AND TELEVISION

Committee on Public Education

ABSTRACT. This statement describes the possible negative health effects of television viewing on children and adolescents, such as violent or aggressive behavior, substance use, sexual activity, obesity, poor body image, and decreased school performance. In addition to the television ratings system and the v-chip (electronic device to block programming), media education is an effective approach to mitigating these potential problems. The American Academy of Pediatrics offers a list of recommendations on this issue for pediatricians and for parents, the federal government, and the entertainment industry. (2/01)

CHILDREN, ADOLESCENTS, AND THE MEDIA

Council on Communications and Media

ABSTRACT. Media, from television to the "new media" (including cell phones, iPads, and social media), are a dominant force in children's lives. Although television is still the predominant medium for children and adolescents, new technologies are increasingly popular. The American Academy of Pediatrics continues to be concerned by evidence about the potential harmful effects of media messages and images; however, important positive and prosocial effects of media use should also be recognized. Pediatricians are encouraged to take a media history and ask 2 media questions at every well-child visit: How much recreational screen time does your child or teenager consume daily? Is there a television set or Internet-connected device in the child's bedroom? Parents are encouraged to establish a family home use plan for all media. Media influences on children and teenagers should be recognized by schools, policymakers, product advertisers, and entertainment producers. (10/13)

CHILDREN, ADOLESCENTS, OBESITY, AND THE MEDIA

Council on Communications and Media

ABSTRACT. Obesity has become a worldwide public health problem. Considerable research has shown that the media contribute to the development of child and adolescent obesity, although the exact mechanism remains

unclear. Screen time may displace more active pursuits, advertising of junk food and fast food increases children's requests for those particular foods and products, snacking increases while watching TV or movies, and late-night screen time may interfere with getting adequate amounts of sleep, which is a known risk factor for obesity. Sufficient evidence exists to warrant a ban on junk-food or fast-food advertising in children's TV programming. Pediatricians need to ask 2 questions about media use at every well-child or well-adolescent visit: (1) How much screen time is being spent per day? and (2) Is there a TV set or Internet connection in the child's bedroom? (7/11)

CHILDREN, ADOLESCENTS, SUBSTANCE ABUSE, AND THE MEDIA

Victor C. Strasburger, MD, and Council on Communications and Media

ABSTRACT. The causes of adolescent substance use are multifactorial, but the media can play a key role. Tobacco and alcohol represent the 2 most significant drug threats to adolescents. More than \$25 billion per year is spent on advertising for tobacco, alcohol, and prescription drugs, and such advertising has been shown to be effective. Digital media are increasingly being used to advertise drugs. In addition, exposure to PG-13- and R-rated movies at an early age may be a major factor in the onset of adolescent tobacco and alcohol use. The American Academy of Pediatrics recommends a ban on all tobacco advertising in all media, limitations on alcohol advertising, avoiding exposure of young children to substance-related (tobacco, alcohol, prescription drugs, illegal drugs) content on television and in PG-13- and R-rated movies, incorporating the topic of advertising and media into all substance abuse-prevention programs, and implementing media education programs in the classroom. (9/10)

CHILDREN AS HEMATOPOIETIC STEM CELL DONORS

Committee on Bioethics

ABSTRACT. In the past half-century, hematopoietic stem cell transplantation has become standard treatment for a variety of diseases in children and adults, including selected hematologic malignancies, immunodeficiencies, hemoglobinopathies, bone marrow failure syndromes, and congenital metabolic disorders. There are 3 sources of allogeneic hematopoietic stem cells: bone marrow, peripheral blood, and umbilical cord blood; each has its own benefits and risks. Children often serve as hematopoietic stem cell donors, most commonly for their siblings. HLA-matched biological siblings are generally preferred as donors because of reduced risks of transplant-related complications as compared with unrelated donors. This statement includes a discussion of the ethical considerations regarding minors serving as stem cell donors, using the traditional benefit/burden calculation from the perspectives of both the donor and the recipient. The statement also includes an examination of the circumstances under which a minor may ethically participate as a hematopoietic stem cell donor, how the risks can be minimized, what the informed-consent process should entail, the role for a donor advocate (or some similar mechanism), and other ethical concerns. The American Academy of

Pediatrics holds that minors can ethically serve as stem cell donors when specific criteria are fulfilled. (1/10)

CHILDREN IN PICKUP TRUCKS

Committee on Injury and Poison Prevention

ABSTRACT. Pickup trucks have become increasingly popular in the United States. A recent study found that in crashes involving fatalities, cargo area passengers were 3 times more likely to die than were occupants in the cab. Compared with restrained cab occupants, the risk of death for those in the cargo area was 8 times higher. Furthermore, the increased use of extended-cab pickup trucks and air bag-equipped front passenger compartments creates concerns about the safe transport of children. The most effective preventive strategies are the legislative prohibition of travel in the cargo area and requirements for age-appropriate restraint use and seat selection in the cab. Parents should select vehicles that are appropriate for the safe transportation needs of the family. Physicians have an important role in counseling families and advocating public policy measures to reduce the number of deaths and injuries to occupants of pickup trucks. (10/00, reaffirmed 5/04, 1/07)

CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP): ACCOMPLISHMENTS, CHALLENGES, AND POLICY RECOMMENDATIONS

Committee on Child Health Financing

ABSTRACT. Sixteen years ago, the 105th Congress, responding to the needs of 10 million children in the United States who lacked health insurance, created the State Children's Health Insurance Program (SCHIP) as part of the Balanced Budget Act of 1997. Enacted as Title XXI of the Social Security Act, the Children's Health Insurance Program (CHIP; or SCHIP as it has been known at some points) provided states with federal assistance to create programs specifically designed for children from families with incomes that exceeded Medicaid thresholds but that were insufficient to enable them to afford private health insurance. Congress provided \$40 billion in block grants over 10 years for states to expand their existing Medicaid programs to cover the intended populations, to erect new stand-alone SCHIP programs for these children, or to effect some combination of both options. Congress reauthorized CHIP once in 2009 under the Children's Health Insurance Program Reauthorization Act and extended its life further within provisions of the Patient Protection and Affordable Care Act of 2010. The purpose of this statement is to review the features of CHIP as it has evolved over the 16 years of its existence; to summarize what is known about the effects that the program has had on coverage, access, health status, and disparities among participants; to identify challenges that remain with respect to insuring this group of vulnerable children, including the impact that provisions of the new Affordable Care Act will have on the issue of health insurance coverage for near-poor children after 2015; and to offer recommendations on how to expand and strengthen the national commitment to provide health insurance to all children regardless of means. (2/14)

See full text on page 547.

CHRONIC ABDOMINAL PAIN IN CHILDREN (CLINICAL REPORT)

Steering Committee on Quality Improvement and Management and Subcommittee on Chronic Abdominal Pain (joint with North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition)

ABSTRACT. Children and adolescents with chronic abdominal pain pose unique challenges to their caregivers. Affected children and their families experience distress and anxiety that can interfere with their ability to perform regular daily activities. Although chronic abdominal pain in children is usually attributable to a functional disorder rather than organic disease, numerous misconceptions, insufficient knowledge among health care professionals, and inadequate application of knowledge may contribute to a lack of effective management. This clinical report accompanies a technical report (see page e370 in this issue) on childhood chronic abdominal pain and provides guidance for the clinician in the evaluation and treatment of children with chronic abdominal pain. The recommendations are based on the evidence reviewed in the technical report and on consensus achieved among subcommittee members. (3/05)

CHRONIC ABDOMINAL PAIN IN CHILDREN (TECHNICAL REPORT)

Steering Committee on Quality Improvement and Management and Subcommittee on Chronic Abdominal Pain (joint with North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition)

ABSTRACT. Chronic abdominal pain, defined as long-lasting intermittent or constant abdominal pain, is a common pediatric problem encountered by primary care physicians, medical subspecialists, and surgical specialists. Chronic abdominal pain in children is usually functional, that is, without objective evidence of an underlying organic disorder. The Subcommittee on Chronic Abdominal Pain of the American Academy of Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition has prepared this report based on a comprehensive, systematic review and rating of the medical literature. This report accompanies a clinical report based on the literature review and expert opinion.

The subcommittee examined the diagnostic and therapeutic value of a medical and psychological history, diagnostic tests, and pharmacologic and behavioral therapy. The presence of alarm symptoms or signs (such as weight loss, gastrointestinal bleeding, persistent fever, chronic severe diarrhea, and significant vomiting) is associated with a higher prevalence of organic disease. There was insufficient evidence to state that the nature of the abdominal pain or the presence of associated symptoms (such as anorexia, nausea, headache, and joint pain) can discriminate between functional and organic disorders. Although children with chronic abdominal pain and their parents are more often anxious or depressed, the presence of anxiety, depression, behavior problems, or recent negative life events does not distinguish between functional and organic abdominal pain. Most children who are brought to the primary care physician's office for chronic abdominal pain are unlikely to require diagnostic testing.

Pediatric studies of therapeutic interventions were examined and found to be limited or inconclusive. (3/05)

CIRCUMCISION POLICY STATEMENT

Task Force on Circumcision

ABSTRACT. Male circumcision is a common procedure, generally performed during the newborn period in the United States. In 2007, the American Academy of Pediatrics (AAP) formed a multidisciplinary task force of AAP members and other stakeholders to evaluate the recent evidence on male circumcision and update the Academy's 1999 recommendations in this area. Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it. Specific benefits identified included prevention of urinary tract infections, penile cancer, and transmission of some sexually transmitted infections, including HIV. The American College of Obstetricians and Gynecologists has endorsed this statement. (8/12)

CLASSIFYING RECOMMENDATIONS FOR CLINICAL PRACTICE GUIDELINES

Steering Committee on Quality Improvement and Management

ABSTRACT. Clinical practice guidelines are intended to improve the quality of clinical care by reducing inappropriate variations, producing optimal outcomes for patients, minimizing harm, and promoting cost-effective practices. This statement proposes an explicit classification of recommendations for clinical practice guidelines of the American Academy of Pediatrics (AAP) to promote communication among guideline developers, implementers, and other users of guideline knowledge, to improve consistency, and to facilitate user understanding. The statement describes 3 sequential activities in developing evidence-based clinical practice guidelines and related policies: 1) determination of the aggregate evidence quality in support of a proposed recommendation; 2) evaluation of the anticipated balance between benefits and harms when the recommendation is carried out; and 3) designation of recommendation strength. An individual policy can be reported as a "strong recommendation," "recommendation," "option," or "no recommendation." Use of this classification is intended to improve consistency and increase the transparency of the guideline-development process, facilitate understanding of AAP clinical practice guidelines, and enhance both the utility and credibility of AAP clinical practice guidelines. (9/04)

CLIMATIC HEAT STRESS AND EXERCISING CHILDREN AND ADOLESCENTS

Council on Sports Medicine and Fitness and Council on School Health

ABSTRACT. Results of new research indicate that, contrary to previous thinking, youth do not have less effective thermoregulatory ability, insufficient cardiovascular capacity, or lower physical exertion tolerance compared with adults during exercise in the heat when adequate hydration is maintained. Accordingly, besides poor hydration status, the primary determinants of reduced performance and exertional heat-illness risk in youth during sports and

other physical activities in a hot environment include undue physical exertion, insufficient recovery between repeated exercise bouts or closely scheduled same-day training sessions or rounds of sports competition, and inappropriately wearing clothing, uniforms, and protective equipment that play a role in excessive heat retention. Because these known contributing risk factors are modifiable, exertional heat illness is usually preventable. With appropriate preparation, modifications, and monitoring, most healthy children and adolescents can safely participate in outdoor sports and other physical activities through a wide range of challenging warm to hot climatic conditions. (8/11)

CLINICAL GENETIC EVALUATION OF THE CHILD WITH MENTAL RETARDATION OR DEVELOPMENTAL DELAYS (CLINICAL REPORT)

John B. Moeschler, MD; Michael Shevell, MD; and Committee on Genetics

ABSTRACT. This clinical report describes the clinical genetic evaluation of the child with developmental delays or mental retardation. The purpose of this report is to describe the optimal clinical genetics diagnostic evaluation to assist pediatricians in providing a medical home for children with developmental delays or mental retardation and their families. The literature supports the benefit of expert clinical judgment by a consulting clinical geneticist in the diagnostic evaluation. However, it is recognized that local factors may preclude this particular option. No single approach to the diagnostic process is supported by the literature. This report addresses the diagnostic importance of clinical history, 3-generation family history, dysmorphicologic examination, neurologic examination, chromosome analysis (≥ 650 bands), fragile X molecular genetic testing, fluorescence in situ hybridization studies for subtelomere chromosome rearrangements, molecular genetic testing for typical and atypical presentations of known syndromes, computed tomography and/or magnetic resonance brain imaging, and targeted studies for metabolic disorders. (6/06, reaffirmed 5/12)

CLOSTRIDIUM DIFFICILE INFECTION IN INFANTS AND CHILDREN

Committee on Infectious Diseases

ABSTRACT. Infections caused by *Clostridium difficile* in hospitalized children are increasing. The recent publication of clinical practice guidelines for *C. difficile* infection in adults did not address issues that are specific to children. The purpose of this policy statement is to provide the pediatrician with updated information and recommendations about *C. difficile* infections affecting pediatric patients. (12/12)

COCHLEAR IMPLANTS IN CHILDREN: SURGICAL SITE INFECTIONS AND PREVENTION AND TREATMENT OF ACUTE OTITIS MEDIA AND MENINGITIS

Lorry G. Rubin, MD; Blake Papsin, MD; Committee on Infectious Diseases; and Section on Otolaryngology–Head and Neck Surgery

ABSTRACT. The use of cochlear implants is increasingly common, particularly in children younger than 3 years. Bacterial meningitis, often with associated acute otitis media, is more common in children with cochlear

implants than in groups of control children. Children with profound deafness who are candidates for cochlear implants should receive all age-appropriate doses of pneumococcal conjugate and *Haemophilus influenzae* type b conjugate vaccines and appropriate annual immunization against influenza. In addition, starting at 24 months of age, a single dose of 23-valent pneumococcal polysaccharide vaccine should be administered. Before implant surgery, primary care providers and cochlear implant teams should ensure that immunizations are up-to-date, preferably with completion of indicated vaccines at least 2 weeks before implant surgery. Imaging of the temporal bone/inner ear should be performed before cochlear implantation in all children with congenital deafness and all patients with profound hearing impairment and a history of bacterial meningitis to identify those with inner-ear malformations/cerebrospinal fluid fistulas or ossification of the cochlea. During the initial months after cochlear implantation, the risk of complications of acute otitis media may be higher than during subsequent time periods. Therefore, it is recommended that acute otitis media diagnosed during the first 2 months after implantation be initially treated with a parenteral antibiotic (eg, ceftriaxone or cefotaxime). Episodes occurring 2 months or longer after implantation can be treated with a trial of an oral antimicrobial agent (eg, amoxicillin or amoxicillin/clavulanate at a dose of approximately 90 mg/kg per day of amoxicillin component), provided the child does not appear toxic and the implant does not have a spacer/positioner, a wedge that rests in the cochlea next to the electrodes present in certain implant models available between 1999 and 2002. "Watchful waiting" without antimicrobial therapy is inappropriate for children with implants with acute otitis media. If feasible, tympanocentesis should be performed for acute otitis media, and the material should be sent for culture, but performance of this procedure should not result in an undue delay in initiating antimicrobial therapy. For patients with suspected meningitis, cerebrospinal fluid as well as middle-ear fluid, if present, should be sent for culture. Empiric antimicrobial therapy for meningitis occurring within 2 months of implantation should include an agent with broad activity against Gram-negative bacilli (eg, meropenem) plus vancomycin. For meningitis occurring 2 months or longer after implantation, standard empiric antimicrobial therapy for meningitis (eg, ceftriaxone plus vancomycin) is indicated. For patients with meningitis, urgent evaluation by an otolaryngologist is indicated for consideration of imaging and surgical exploration. (7/10)

COLLABORATIVE ROLE OF THE PEDIATRICIAN IN THE DIAGNOSIS AND MANAGEMENT OF BIPOLAR DISORDER IN ADOLESCENTS (CLINICAL REPORT)

Benjamin N. Shain, MD, PhD, and Committee on Adolescence

ABSTRACT. Despite the complexity of diagnosis and management, pediatricians have an important collaborative role in referring and partnering in the management of adolescents with bipolar disorder. This report presents the classification of bipolar disorder as well as interviewing and diagnostic guidelines. Treatment options are described, particularly focusing on medication management and rationale for the common practice of multiple,

simultaneous medications. Medication adverse effects may be problematic and better managed with collaboration between mental health professionals and pediatricians. Case examples illustrate a number of common diagnostic and management issues. (11/12)

COMMUNICATING WITH CHILDREN AND FAMILIES: FROM EVERYDAY INTERACTIONS TO SKILL IN CONVEYING DISTRESSING INFORMATION (TECHNICAL REPORT)

Marcia Levetown, MD, and Committee on Bioethics

ABSTRACT. Health care communication is a skill that is critical to safe and effective medical practice; it can and must be taught. Communication skill influences patient disclosure, treatment adherence and outcome, adaptation to illness, and bereavement. This article provides a review of the evidence regarding clinical communication in the pediatric setting, covering the spectrum from outpatient primary care consultation to death notification, and provides practical suggestions to improve communication with patients and families, enabling more effective, efficient, and empathic pediatric health care. (5/08, reaffirmed 5/11)

COMMUNITY PEDIATRICS: NAVIGATING THE INTERSECTION OF MEDICINE, PUBLIC HEALTH, AND SOCIAL DETERMINANTS OF CHILDREN'S HEALTH

Council on Community Pediatrics

ABSTRACT. This policy statement provides a framework for the pediatrician's role in promoting the health and well-being of all children in the context of their families and communities. It offers pediatricians a definition of community pediatrics, emphasizes the importance of recognizing social determinants of health, and delineates the need to partner with public health to address population-based child health issues. It also recognizes the importance of pediatric involvement in child advocacy at local, state, and federal levels to ensure all children have access to a high-quality medical home and to eliminate child health disparities. This statement provides a set of specific recommendations that underscore the critical nature of this dimension of pediatric practice, teaching, and research. (2/13)

COMPREHENSIVE EVALUATION OF THE CHILD WITH INTELLECTUAL DISABILITY OR GLOBAL DEVELOPMENTAL DELAYS (CLINICAL REPORT)

John B. Moeschler, MD, MS, FAAP, FACMG; Michael Shevell, MDCM, FRCP; and Committee on Genetics

ABSTRACT. Global developmental delay and intellectual disability are relatively common pediatric conditions. This report describes the recommended clinical genetics diagnostic approach. The report is based on a review of published reports, most consisting of medium to large case series of diagnostic tests used, and the proportion of those that led to a diagnosis in such patients. Chromosome microarray is designated as a first-line test and replaces the standard karyotype and fluorescent in situ hybridization subtelomere tests for the child with intellectual disability of unknown etiology. Fragile X testing remains an important first-line test. The importance of considering testing for inborn errors of metabolism in this population

is supported by a recent systematic review of the literature and several case series recently published. The role of brain MRI remains important in certain patients. There is also a discussion of the emerging literature on the use of whole-exome sequencing as a diagnostic test in this population. Finally, the importance of intentional comanagement among families, the medical home, and the clinical genetics specialty clinic is discussed. (8/14)

See full text on page 559.

COMPREHENSIVE HEALTH EVALUATION OF THE NEWLY ADOPTED CHILD (CLINICAL REPORT)

Veronnie F. Jones, MD, PhD, MSPH, and Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. Children who join families through the process of adoption often have multiple health care needs. After placement in an adoptive home, it is essential that these children have a timely comprehensive health evaluation. This evaluation should include a review of all available medical records and a complete physical examination. Evaluation should also include diagnostic testing based on the findings from the history and physical examination as well as the risks presented by the child's previous living conditions. Age-appropriate screens should be performed, including, for example, newborn screening panels, hearing, vision, dental, and formal behavioral/developmental screens. The comprehensive assessment can occur at the time of the initial visit to the physician after adoptive placement or can take place over several visits. Adopted children should be referred to other medical specialists as deemed appropriate. The Section on Adoption and Foster Care is a resource within the American Academy of Pediatrics for physicians providing care for children who are being adopted. (12/11)

CONDOM USE BY ADOLESCENTS

Committee on Adolescence

ABSTRACT. Rates of sexual activity, pregnancies, and births among adolescents have continued to decline during the past decade to historic lows. Despite these positive trends, many adolescents remain at risk for unintended pregnancy and sexually transmitted infections (STIs). This policy statement has been developed to assist the pediatrician in understanding and supporting the use of condoms by their patients to prevent unintended pregnancies and STIs and address barriers to their use. When used consistently and correctly, male latex condoms reduce the risk of pregnancy and many STIs, including HIV. Since the last policy statement published 12 years ago, there is an increased evidence base supporting the protection provided by condoms against STIs. Rates of acquisition of STIs/HIV among adolescents remain unacceptably high. Interventions that increase availability or accessibility to condoms are most efficacious when combined with additional individual, small-group, or community-level activities that include messages about safer sex. Continued research is needed to inform public health interventions for adolescents that increase the consistent and correct use of condoms and promote dual protection of condoms for STI prevention with other effective methods of contraception. (10/13)

CONFLICTS BETWEEN RELIGIOUS OR SPIRITUAL BELIEFS AND PEDIATRIC CARE: INFORMED REFUSAL, EXEMPTIONS, AND PUBLIC FUNDING

Committee on Bioethics

ABSTRACT. Although respect for parents' decision-making authority is an important principle, pediatricians should report suspected cases of medical neglect, and the state should, at times, intervene to require medical treatment of children. Some parents' reasons for refusing medical treatment are based on their religious or spiritual beliefs. In cases in which treatment is likely to prevent death or serious disability or relieve severe pain, children's health and future autonomy should be protected. Because religious exemptions to child abuse and neglect laws do not equally protect all children and may harm some children by causing confusion about the duty to provide medical treatment, these exemptions should be repealed. Furthermore, public health care funds should not cover alternative unproven religious or spiritual healing practices. Such payments may inappropriately legitimize these practices as appropriate medical treatment. (10/13)

CONGENITAL ADRENAL HYPERPLASIA (TECHNICAL REPORT)

Section on Endocrinology and Committee on Genetics

ABSTRACT. The Section on Endocrinology and the Committee on Genetics of the American Academy of Pediatrics, in collaboration with experts from the field of pediatric endocrinology and genetics, developed this policy statement as a means of providing up-to-date information for the practicing pediatrician about current practice and controversial issues in congenital adrenal hyperplasia (CAH), including the current status of prenatal diagnosis and treatment, the benefits and problem areas of neonatal screening programs, and the management of children with nonclassic CAH. The reference list is designed to allow physicians who wish more information to research the topic more thoroughly. (12/00, reaffirmed 10/04)

A CONSENSUS STATEMENT ON HEALTH CARE TRANSITIONS FOR YOUNG ADULTS WITH SPECIAL HEALTH CARE NEEDS

American Academy of Pediatrics, American Academy of Family Physicians, and American College of Physicians-American Society of Internal Medicine

ABSTRACT. This policy statement represents a consensus on the critical first steps that the medical profession needs to take to realize the vision of a family-centered, continuous, comprehensive, coordinated, compassionate, and culturally competent health care system that is as developmentally appropriate as it is technically sophisticated. The goal of transition in health care for young adults with special health care needs is to maximize lifelong functioning and potential through the provision of high-quality, developmentally appropriate health care services that continue uninterrupted as the individual moves from adolescence to adulthood. This consensus document has now been approved as policy by the boards of the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians-American Society of Internal Medicine. (12/02)

CONSENT BY PROXY FOR NONURGENT PEDIATRIC CARE (CLINICAL REPORT)

Gary N. McAbee, DO, JD, and Committee on Medical Liability and Risk Management

ABSTRACT. Minor-aged patients are often brought to the pediatrician for nonurgent acute medical care, physical examinations, or health supervision visits by someone other than their legally authorized representative, which, in most situations, is a parent. These surrogates or proxies can be members of the child's extended family, such as a grandparent, adult sibling, or aunt/uncle; a noncustodial parent or stepparent in cases of divorce and remarriage; an adult who lives in the home but is not biologically or legally related to the child; or even a child care professional (eg, au pair, nanny). This report identifies common situations in which pediatricians may encounter "consent by proxy" for nonurgent medical care for minors, including physical examinations, and explains the potential for liability exposure associated with these circumstances. The report suggests practical steps that balance the need to minimize the physician's liability exposure with the patient's access to health care. Key issues to be considered when creating or updating office policies for obtaining and documenting consent by proxy are offered. (10/10)

CONSENT FOR EMERGENCY MEDICAL SERVICES FOR CHILDREN AND ADOLESCENTS

Committee on Pediatric Emergency Medicine and Committee on Bioethics

ABSTRACT. Parental consent generally is required for the medical evaluation and treatment of minor children. However, children and adolescents might require evaluation of and treatment for emergency medical conditions in situations in which a parent or legal guardian is not available to provide consent or conditions under which an adolescent patient might possess the legal authority to provide consent. In general, a medical screening examination and any medical care necessary and likely to prevent imminent and significant harm to the pediatric patient with an emergency medical condition should not be withheld or delayed because of problems obtaining consent. The purpose of this policy statement is to provide guidance in those situations in which parental consent is not readily available, in which parental consent is not necessary, or in which parental refusal of consent places a child at risk of significant harm. (7/11)

CONSUMPTION OF RAW OR UNPASTEURIZED MILK AND MILK PRODUCTS BY PREGNANT WOMEN AND CHILDREN

Committee on Infectious Diseases and Committee on Nutrition

ABSTRACT. Sales of raw or unpasteurized milk and milk products are still legal in at least 30 states in the United States. Raw milk and milk products from cows, goats, and sheep continue to be a source of bacterial infections attributable to a number of virulent pathogens, including *Listeria monocytogenes*, *Campylobacter jejuni*, *Salmonella* species, *Brucella* species, and *Escherichia coli* O157. These infections can occur in both healthy and immunocompromised individuals, including older adults, infants, young children, and pregnant women and their unborn fetuses, in

whom life-threatening infections and fetal miscarriage can occur. Efforts to limit the sale of raw milk products have met with opposition from those who are proponents of the purported health benefits of consuming raw milk products, which contain natural or unprocessed factors not inactivated by pasteurization. However, the benefits of these natural factors have not been clearly demonstrated in evidence-based studies and, therefore, do not outweigh the risks of raw milk consumption. Substantial data suggest that pasteurized milk confers equivalent health benefits compared with raw milk, without the additional risk of bacterial infections. The purpose of this policy statement was to review the risks of raw milk consumption in the United States and to provide evidence of the risks of infectious complications associated with consumption of unpasteurized milk and milk products, especially among pregnant women, infants, and children. (12/13)

CONTRACEPTION FOR ADOLESCENTS

Committee on Adolescence

ABSTRACT. Contraception is a pillar in reducing adolescent pregnancy rates. The American Academy of Pediatrics recommends that pediatricians develop a working knowledge of contraception to help adolescents reduce risks of and negative health consequences related to unintended pregnancy. Over the past 10 years, a number of new contraceptive methods have become available to adolescents, newer guidance has been issued on existing contraceptive methods, and the evidence base for contraception for special populations (adolescents who have disabilities, are obese, are recipients of solid organ transplants, or are HIV infected) has expanded. The Academy has addressed contraception since 1980, and this policy statement updates the 2007 statement on contraception and adolescents. It provides the pediatrician with a description and rationale for best practices in counseling and prescribing contraception for adolescents. It is supported by an accompanying technical report. (9/14)

See full text on page 577.

CONTRACEPTION FOR ADOLESCENTS (TECHNICAL REPORT)

Mary A. Ott, MD, MA, FAAP; Gina S. Sucato, MD, MPH, FAAP; and Committee on Adolescence

ABSTRACT. A working knowledge of contraception will assist the pediatrician in both sexual health promotion as well as treatment of common adolescent gynecologic problems. Best practices in adolescent anticipatory guidance and screening include a sexual health history, screening for pregnancy and sexually transmitted infections, counseling, and if indicated, providing access to contraceptives. Pediatricians' long-term relationships with adolescents and families allow them to help promote healthy sexual decision-making, including abstinence and contraceptive use. Additionally, medical indications for contraception, such as acne, dysmenorrhea, and heavy menstrual bleeding, are frequently uncovered during adolescent visits. This technical report provides an evidence base for the accompanying policy statement and addresses key aspects of adolescent contraceptive use, including the following: (1) sexual history taking, confidentiality, and counseling; (2) adolescent data on the use and side effects

of newer contraceptive methods; (3) new data on older contraceptive methods; and (4) evidence supporting the use of contraceptives in adolescent patients with complex medical conditions. (9/14)

See full text on page 593.

CONTROVERSIES CONCERNING VITAMIN K AND THE NEWBORN

Committee on Fetus and Newborn

ABSTRACT. Prevention of early vitamin K deficiency bleeding (VKDB) of the newborn, with onset at birth to 2 weeks of age (formerly known as classic hemorrhagic disease of the newborn), by oral or parenteral administration of vitamin K is accepted practice. In contrast, late VKDB, with onset from 2 to 12 weeks of age, is most effectively prevented by parenteral administration of vitamin K. Earlier concern regarding a possible causal association between parenteral vitamin K and childhood cancer has not been substantiated. This revised statement presents updated recommendations for the use of vitamin K in the prevention of early and late VKDB. (7/03, reaffirmed 5/06, 5/09)

COPARENT OR SECOND-PARENT ADOPTION BY SAME-SEX PARENTS

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Children who are born to or adopted by 1 member of a same-sex couple deserve the security of 2 legally recognized parents. Therefore, the American Academy of Pediatrics supports legislative and legal efforts to provide the possibility of adoption of the child by the second parent or coparent in these families. (2/02, reaffirmed 5/09)

COPARENT OR SECOND-PARENT ADOPTION BY SAME-SEX PARENTS (TECHNICAL REPORT)

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. A growing body of scientific literature demonstrates that children who grow up with 1 or 2 gay and/or lesbian parents fare as well in emotional, cognitive, social, and sexual functioning as do children whose parents are heterosexual. Children's optimal development seems to be influenced more by the nature of the relationships and interactions within the family unit than by the particular structural form it takes. (2/02, reaffirmed 5/09)

CORPORAL PUNISHMENT IN SCHOOLS

Committee on School Health

ABSTRACT. The American Academy of Pediatrics recommends that corporal punishment in schools be abolished in all states by law and that alternative forms of student behavior management be used. (8/00, reaffirmed 6/03, 5/06, 2/12)

COUNSELING FAMILIES WHO CHOOSE COMPLEMENTARY AND ALTERNATIVE MEDICINE FOR THEIR CHILD WITH CHRONIC ILLNESS OR DISABILITY

Committee on Children With Disabilities

ABSTRACT. The use of complementary and alternative medicine (CAM) to treat chronic illness or disability is increasing in the United States. This is especially evident among children with autism and related disorders. It may

be challenging to the practicing pediatrician to distinguish among accepted biomedical treatments, unproven therapies, and alternative therapies. Moreover, there are no published guidelines regarding the use of CAM in the care of children with chronic illness or disability. To best serve the interests of children, it is important to maintain a scientific perspective, to provide balanced advice about therapeutic options, to guard against bias, and to establish and maintain a trusting relationship with families. This statement provides information and guidance for pediatricians when counseling families about CAM. (3/01, reaffirmed 1/05, 5/10)

COUNSELING THE ADOLESCENT ABOUT PREGNANCY OPTIONS

Committee on Adolescence

ABSTRACT. When consulted by a pregnant adolescent, pediatricians should be able to make a timely diagnosis and to help the adolescent understand her options and act on her decision to continue or terminate her pregnancy. Pediatricians may not impose their values on the decision-making process and should be prepared to support the adolescent in her decision or refer her to a physician who can. (5/98, reaffirmed 1/01, 1/06)

CREATING HEALTHY CAMP EXPERIENCES

Council on School Health

ABSTRACT. The American Academy of Pediatrics has created recommendations for health appraisal and preparation of young people before participation in day or resident camps and to guide health and safety practices for children at camp. These recommendations are intended for parents, primary health care providers, and camp administration and health center staff. Although camps have diverse environments, there are general guidelines that apply to all situations and specific recommendations that are appropriate under special conditions. This policy statement has been reviewed and is supported by the American Camp Association. (3/11)

THE CRUCIAL ROLE OF RECESS IN SCHOOL

Council on School Health

ABSTRACT. Recess is at the heart of a vigorous debate over the role of schools in promoting the optimal development of the whole child. A growing trend toward real-locating time in school to accentuate the more academic subjects has put this important facet of a child's school day at risk. Recess serves as a necessary break from the rigors of concentrated, academic challenges in the classroom. But equally important is the fact that safe and well-supervised recess offers cognitive, social, emotional, and physical benefits that may not be fully appreciated when a decision is made to diminish it. Recess is unique from, and a complement to, physical education—not a substitute for it. The American Academy of Pediatrics believes that recess is a crucial and necessary component of a child's development and, as such, it should not be withheld for punitive or academic reasons. (12/12)

DEALING WITH THE PARENT WHOSE JUDGMENT IS IMPAIRED BY ALCOHOL OR DRUGS: LEGAL AND ETHICAL CONSIDERATIONS (CLINICAL REPORT)

Committee on Medical Liability

ABSTRACT. An estimated 11 to 17.5 million children are being raised by a substance-abusing parent or guardian. The importance of this statistic is undeniable, particularly when a patient is brought to a pediatric office by a parent or guardian exhibiting symptoms of judgment impairment. Although the physician-patient relationship exists between the pediatrician and the minor patient, other obligations (some perceived and some real) should be considered as well. In managing encounters with impaired parents who may become disruptive or dangerous, pediatricians should be aware of their responsibilities before acting. In addition to fulfilling the duty involved with an established physician-patient relationship, the pediatrician should take reasonable care to safeguard patient confidentiality; protect the safety of the patient and other patients, visitors, and employees; and comply with reporting mandates. This clinical report identifies and discusses the legal and ethical concepts related to these circumstances. The report offers implementation suggestions when establishing anticipatory office procedures and training programs for staff on what to do (and not do) in such situations to maximize the patient's well-being and safety and minimize the liability of the pediatrician. (9/04, reaffirmed 9/10)

DEATH OF A CHILD IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. The American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association have collaborated to identify practices and principles to guide the care of children, families, and staff in the challenging and uncommon event of the death of a child in the emergency department in this policy statement and in an accompanying technical report. (6/14)

See full text on page 621.

DEATH OF A CHILD IN THE EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Patricia O'Malley, MD; Isabel Barata, MD; Sally Snow, RN; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. The death of a child in the emergency department (ED) is one of the most challenging problems facing ED clinicians. This revised technical report and accompanying policy statement reaffirm principles of patient- and family-centered care. Recent literature is examined regarding family presence, termination of resuscitation, bereavement responsibilities of ED clinicians, support of child fatality review efforts, and other issues inherent in caring for the patient, family, and staff when a child dies in the ED. Appendices are provided that offer an approach to bereavement activities in the ED, carrying out forensic

responsibilities while providing compassionate care, communicating the news of the death of a child in the acute setting, providing a closing ritual at the time of terminating resuscitation efforts, and managing the child with a terminal condition who presents near death in the ED. (6/14)

See full text on page 627.

DEVELOPMENTAL DYSPLASIA OF THE HIP PRACTICE GUIDELINE (TECHNICAL REPORT)

Harold P. Lehmann, MD, PhD; Richard Hinton, MD, MPH; Paola Morello, MD; Jeanne Santoli, MD; in conjunction with Steering Committee on Quality Improvement and Subcommittee on Developmental Dysplasia of the Hip

ABSTRACT. *Objective.* To create a recommendation for pediatricians and other primary care providers about their role as screeners for detecting developmental dysplasia of the hip (DDH) in children.

Patients. Theoretical cohorts of newborns.

Method. Model-based approach using decision analysis as the foundation. Components of the approach include the following:

Perspective: Primary care provider.

Outcomes: DDH, avascular necrosis of the hip (AVN).

Options: Newborn screening by pediatric examination; orthopaedic examination; ultrasonographic examination; orthopaedic or ultrasonographic examination by risk factors. Intercurrent health supervision-based screening.

Preferences: 0 for bad outcomes, 1 for best outcomes.

Model: Influence diagram assessed by the Subcommittee and by the methodology team, with critical feedback from the Subcommittee.

Evidence Sources: Medline and EMBASE search of the research literature through June 1996. Hand search of sentinel journals from June 1996 through March 1997. Ancestor search of accepted articles.

Evidence Quality: Assessed on a custom subjective scale, based primarily on the fit of the evidence to the decision model.

Results. After discussion, explicit modeling, and critique, an influence diagram of 31 nodes was created. The computer-based and the hand literature searches found 534 articles, 101 of which were reviewed by 2 or more readers. Ancestor searches of these yielded a further 17 articles for evidence abstraction. Articles came from around the globe, although primarily Europe, British Isles, Scandinavia, and their descendants. There were 5 controlled trials, each with a sample size less than 40. The remainder were case series. Evidence was available for 17 of the desired 30 probabilities. Evidence quality ranged primarily between one third and two thirds of the maximum attainable score (median: 10–21; interquartile range: 8–14). Based on the raw evidence and Bayesian hierarchical meta-analyses, our estimate for the incidence of DDH revealed by physical examination performed by pediatricians is 8.6 per 1000; for orthopaedic screening, 11.5; for ultrasonography, 25. The odds ratio for DDH, given breech delivery, is 5.5; for female sex, 4.1; for positive family history, 1.7, although this last factor is not statistically significant. Postneonatal cases of DDH were divided into mid-term (younger than 6 months of age) and late-

term (older than 6 months of age). Our estimates for the mid-term rate for screening by pediatricians is 0.34/1000 children screened; for orthopaedists, 0.1; and for ultrasonography, 0.28. Our estimates for late-term DDH rates are 0.21/1000 newborns screened by pediatricians; 0.08, by orthopaedists; and 0.2 for ultrasonography. The rates of AVN for children referred before 6 months of age is estimated at 2.5/1000 infants referred. For those referred after 6 months of age, our estimate is 109/1000 referred infants. The decision model (reduced, based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ, the supply of orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is statistically insignificant, we conclude that pediatric screening is to be recommended. The place of ultrasonography in the screening process remains to be defined because there are too few data about postneonatal diagnosis by ultrasonographic screening to permit definitive recommendations. These data could be used by others to refine the conclusions based on costs, parental preferences, or physician style. Areas for research are well defined by our model-based approach. (4/00)

DIAGNOSIS AND MANAGEMENT OF AN INITIAL UTI IN FEBRILE INFANTS AND YOUNG CHILDREN (TECHNICAL REPORT)



S. Maria E. Finnell, MD, MS; Aaron E. Carroll, MD, MS; Stephen M. Downs, MD, MS; Steering Committee on Quality Improvement and Management; and Subcommittee on Urinary Tract Infection

ABSTRACT. *Objectives.* The diagnosis and management of urinary tract infections (UTIs) in young children are clinically challenging. This report was developed to inform the revised, evidence-based, clinical guideline regarding the diagnosis and management of initial UTIs in febrile infants and young children, 2 to 24 months of age, from the American Academy of Pediatrics Subcommittee on Urinary Tract Infection.

Methods. The conceptual model presented in the 1999 technical report was updated after a comprehensive review of published literature. Studies with potentially new information or with evidence that reinforced the 1999 technical report were retained. Meta-analyses on the effectiveness of antimicrobial prophylaxis to prevent recurrent UTI were performed.

Results. Review of recent literature revealed new evidence in the following areas. Certain clinical findings and new urinalysis methods can help clinicians identify febrile children at very low risk of UTI. Oral antimicrobial therapy is as effective as parenteral therapy in treating UTI. Data from published, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI when vesicoureteral reflux is found through voiding cystourethrography. Ultrasonography of the urinary tract after the first UTI has poor sensitivity. Early antimicrobial treatment may decrease the risk of renal damage from UTI.

Conclusions. Recent literature agrees with most of the evidence presented in the 1999 technical report, but meta-analyses of data from recent, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI. This finding argues against voiding cystourethrography after the first UTI. (8/11)

DIAGNOSIS AND MANAGEMENT OF CHILDHOOD OBSTRUCTIVE SLEEP APNEA SYNDROME (TECHNICAL REPORT)

Carole L. Marcus, MBBCh; Lee J. Brooks, MD; Sally Davidson Ward, MD; Kari A. Draper, MD; David Gozal, MD; Ann C. Halbower, MD; Jacqueline Jones, MD; Christopher Lehmann, MD; Michael S. Schechter, MD, MPH; Stephen Sheldon, MD; Richard N. Shiffman, MD, MCIS; Karen Spruyt, PhD; Steering Committee on Quality Improvement and Management; and Subcommittee on Obstructive Sleep Apnea Syndrome

ABSTRACT. *Objective.* This technical report describes the procedures involved in developing recommendations on the management of childhood obstructive sleep apnea syndrome (OSAS).

Methods. The literature from 1999 through 2011 was evaluated.

Results and Conclusions. A total of 3166 titles were reviewed, of which 350 provided relevant data. Most articles were level II through IV. The prevalence of OSAS ranged from 0% to 5.7%, with obesity being an independent risk factor. OSAS was associated with cardiovascular, growth, and neurobehavioral abnormalities and possibly inflammation. Most diagnostic screening tests had low sensitivity and specificity. Treatment of OSAS resulted in improvements in behavior and attention and likely improvement in cognitive abilities. Primary treatment is adenotonsillectomy (AT). Data were insufficient to recommend specific surgical techniques; however, children undergoing partial tonsillectomy should be monitored for possible recurrence of OSAS. Although OSAS improved postoperatively, the proportion of patients who had residual OSAS ranged from 13% to 29% in low-risk populations to 73% when obese children were included and stricter polysomnographic criteria were used. Nevertheless, OSAS may improve after AT even in obese children, thus supporting surgery as a reasonable initial treatment. A significant number of obese patients required intubation or continuous positive airway pressure (CPAP) postoperatively, which reinforces the need for inpatient observation. CPAP was effective in the treatment of OSAS, but adherence is a major barrier. For this reason, CPAP is not recommended as first-line therapy for OSAS when AT is an option. Intranasal steroids may ameliorate mild OSAS, but follow-up is needed. Data were insufficient to recommend rapid maxillary expansion. (8/12)

DIAGNOSIS AND PREVENTION OF IRON DEFICIENCY AND IRON-DEFICIENCY ANEMIA IN INFANTS AND YOUNG CHILDREN (0–3 YEARS OF AGE) (CLINICAL REPORT)

Robert D. Baker, MD, PhD; Frank R. Greer, MD; and Committee on Nutrition

ABSTRACT. This clinical report covers diagnosis and prevention of iron deficiency and iron-deficiency anemia

in infants (both breastfed and formula fed) and toddlers from birth through 3 years of age. Results of recent basic research support the concerns that iron-deficiency anemia and iron deficiency without anemia during infancy and childhood can have long-lasting detrimental effects on neurodevelopment. Therefore, pediatricians and other health care providers should strive to eliminate iron deficiency and iron-deficiency anemia. Appropriate iron intakes for infants and toddlers as well as methods for screening for iron deficiency and iron-deficiency anemia are presented. (10/10)

DIAGNOSIS OF HIV-1 INFECTION IN CHILDREN YOUNGER THAN 18 MONTHS IN THE UNITED STATES (TECHNICAL REPORT)

Jennifer S. Read, MD, MS, MPH, DTM&H, and Committee on Pediatric AIDS

ABSTRACT. The objectives of this technical report are to describe methods of diagnosis of HIV-1 infection in children younger than 18 months in the United States and to review important issues that must be considered by clinicians who care for infants and young children born to HIV-1-infected women. Appropriate HIV-1 diagnostic testing for infants and children younger than 18 months differs from that for older children, adolescents, and adults because of passively transferred maternal HIV-1 antibodies, which may be detectable in the child's bloodstream until 18 months of age. Therefore, routine serologic testing of these infants and young children is generally only informative before the age of 18 months if the test result is negative. Virologic assays, including HIV-1 DNA or RNA assays, represent the gold standard for diagnostic testing of infants and children younger than 18 months. With such testing, the diagnosis of HIV-1 infection (as well as the presumptive exclusion of HIV-1 infection) can be established within the first several weeks of life among nonbreastfed infants. Important factors that must be considered when selecting HIV-1 diagnostic assays for pediatric patients and when choosing the timing of such assays include the age of the child, potential timing of infection of the child, whether the infection status of the child's mother is known or unknown, the antiretroviral exposure history of the mother and of the child, and characteristics of the virus. If the mother's HIV-1 serostatus is unknown, rapid HIV-1 antibody testing of the newborn infant to identify HIV-1 exposure is essential so that antiretroviral prophylaxis can be initiated within the first 12 hours of life if test results are positive. For HIV-1-exposed infants (identified by positive maternal test results or positive antibody results for the infant shortly after birth), it has been recommended that diagnostic testing with HIV-1 DNA or RNA assays be performed within the first 14 days of life, at 1 to 2 months of age, and at 3 to 6 months of age. If any of these test results are positive, repeat testing is recommended to confirm the diagnosis of HIV-1 infection. A diagnosis of HIV-1 infection can be made on the basis of 2 positive HIV-1 DNA or RNA assay results. In nonbreastfeeding children younger than 18 months with no positive HIV-1 virologic test results, presumptive exclusion of HIV-1 infection can be based on 2 negative virologic test results (1 obtained at ≥ 2 weeks and 1 obtained at ≥ 4 weeks of age); 1 negative virologic test result obtained at ≥ 8 weeks

of age; or 1 negative HIV-1 antibody test result obtained at ≥ 6 months of age. Alternatively, presumptive exclusion of HIV-1 infection can be based on 1 positive HIV-1 virologic test with at least 2 subsequent negative virologic test results (at least 1 of which is performed at ≥ 8 weeks of age) or negative HIV-1 antibody test results (at least 1 of which is performed at ≥ 6 months of age). Definitive exclusion of HIV-1 infection is based on 2 negative virologic test results, 1 obtained at ≥ 1 month of age and 1 obtained at ≥ 4 months of age, or 2 negative HIV-1 antibody test results from separate specimens obtained at ≥ 6 months of age. For both presumptive and definitive exclusion of infection, the child should have no other laboratory (eg, no positive virologic test results) or clinical (eg, no AIDS-defining conditions) evidence of HIV-1 infection. Many clinicians confirm the absence of HIV-1 infection with a negative HIV-1 antibody assay result at 12 to 18 months of age. For breastfeeding infants, a similar testing algorithm can be followed, with timing of testing starting from the date of complete cessation of breastfeeding instead of the date of birth. (12/07, reaffirmed 4/10)

DIAGNOSTIC IMAGING OF CHILD ABUSE

Section on Radiology

ABSTRACT. The role of imaging in cases of child abuse is to identify the extent of physical injury when abuse is present and to elucidate all imaging findings that point to alternative diagnoses. Effective diagnostic imaging of child abuse rests on high-quality technology as well as a full appreciation of the clinical and pathologic alterations occurring in abused children. This statement is a revision of the previous policy published in 2000. (4/09)

DISASTER PLANNING FOR SCHOOLS

Council on School Health

ABSTRACT. Community awareness of the school district's disaster plan will optimize a community's capacity to maintain the safety of its school-aged population in the event of a school-based or greater community crisis. This statement is intended to stimulate awareness of the disaster-preparedness process in schools as a part of a global, community-wide preparedness plan. Pediatricians, other health care professionals, first responders, public health officials, the media, school nurses, school staff, and parents all need to be unified in their efforts to support schools in the prevention of, preparedness for, response to, and recovery from a disaster. (10/08, reaffirmed 9/11)

DISCLOSURE OF ILLNESS STATUS TO CHILDREN AND ADOLESCENTS WITH HIV INFECTION

Committee on Pediatric AIDS

ABSTRACT. Many children with human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome are surviving to middle childhood and adolescence. Studies suggest that children who know their HIV status have higher self-esteem than children who are unaware of their status. Parents who have disclosed the status to their children experience less depression than those who do not. This statement addresses our current knowledge and recommendations for disclosure of HIV infection status to children and adolescents. (1/99, reaffirmed 2/02, 5/05, 1/09, 1/12)

DISPENSING MEDICATIONS AT THE HOSPITAL UPON DISCHARGE FROM AN EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Loren G. Yamamoto, MD, MPH, MBA; Shannon Manzi,

PharmD; and Committee on Pediatric Emergency Medicine
ABSTRACT. Although most health care services can and should be provided by their medical home, children will be referred or require visits to the emergency department (ED) for emergent clinical conditions or injuries. Continuation of medical care after discharge from an ED is dependent on parents or caregivers' understanding of and compliance with follow-up instructions and on adherence to medication recommendations. ED visits often occur at times when the majority of pharmacies are not open and caregivers are concerned with getting their ill or injured child directly home. Approximately one-third of patients fail to obtain priority medications from a pharmacy after discharge from an ED. The option of judiciously dispensing ED discharge medications from the ED's outpatient pharmacy within the facility is a major convenience that overcomes this obstacle, improving the likelihood of medication adherence. Emergency care encounters should be routinely followed up with primary care provider medical homes to ensure complete and comprehensive care. (1/12)

DISTINGUISHING SUDDEN INFANT DEATH SYNDROME FROM CHILD ABUSE FATALITIES (CLINICAL REPORT)

Kent P. Hymel, MD, and Committee on Child Abuse and

Neglect (joint with National Association of Medical Examiners)

ABSTRACT. Fatal child abuse has been mistaken for sudden infant death syndrome. When a healthy infant younger than 1 year dies suddenly and unexpectedly, the cause of death may be certified as sudden infant death syndrome. Sudden infant death syndrome is more common than infanticide. Parents of sudden infant death syndrome victims typically are anxious to provide unlimited information to professionals involved in death investigation or research. They also want and deserve to be approached in a nonaccusatory manner. This clinical report provides professionals with information and suggestions for procedures to help avoid stigmatizing families of sudden infant death syndrome victims while allowing accumulation of appropriate evidence in potential cases of infanticide. This clinical report addresses deficiencies and updates recommendations in the 2001 American Academy of Pediatrics policy statement of the same name. (7/06, reaffirmed 4/09, 3/13)

DO-NOT-RESUSCITATE ORDERS FOR PEDIATRIC PATIENTS WHO REQUIRE ANESTHESIA AND SURGERY (CLINICAL REPORT)

Section on Surgery, Section on Anesthesia and Pain Medicine, and Committee on Bioethics

ABSTRACT. This clinical report addresses the topic of preexisting do-not-resuscitate (DNR) orders for children undergoing anesthesia and surgery. Pertinent issues addressed include the rights of children, surrogate decision-making, the process of informed consent, and the roles of surgeons and anesthesiologists. The reevaluation process of DNR orders called "required reconsideration"

can be incorporated into the process of informed consent for surgery and anesthesia. Care should be taken to distinguish between goal-directed and procedure-directed approaches to DNR orders. By giving parents or other surrogates and clinicians the option of deciding from among full resuscitation, limitations based on procedures, or limitations based on goals, the child's needs are individualized and better served. (12/04, reaffirmed 1/09, 10/12)

DRINKING WATER FROM PRIVATE WELLS AND RISKS TO CHILDREN

Committee on Environmental Health and Committee on Infectious Diseases

ABSTRACT. Drinking water for approximately one sixth of US households is obtained from private wells. These wells can become contaminated by pollutant chemicals or pathogenic organisms and cause illness. Although the US Environmental Protection Agency and all states offer guidance for construction, maintenance, and testing of private wells, there is little regulation. With few exceptions, well owners are responsible for their own wells. Children may also drink well water at child care or when traveling. Illness resulting from children's ingestion of contaminated water can be severe. This policy statement provides recommendations for inspection, testing, and remediation for wells providing drinking water for children. (5/09, reaffirmed 1/13)

DRINKING WATER FROM PRIVATE WELLS AND RISKS TO CHILDREN (TECHNICAL REPORT)

Walter J. Rogan, MD; Michael T. Brady, MD; Committee on Environmental Health; and Committee on Infectious Diseases

ABSTRACT. Drinking water for approximately one sixth of US households is obtained from private wells. These wells can become contaminated by pollutant chemicals or pathogenic organisms, leading to significant illness. Although the US Environmental Protection Agency and all states offer guidance for construction, maintenance, and testing of private wells, there is little regulation, and with few exceptions, well owners are responsible for their own wells. Children may also drink well water at child care or when traveling. Illness resulting from children's ingestion of contaminated water can be severe. This report reviews relevant aspects of groundwater and wells; describes the common chemical and microbiologic contaminants; gives an algorithm with recommendations for inspection, testing, and remediation for wells providing drinking water for children; reviews the definitions and uses of various bottled waters; provides current estimates of costs for well testing; and provides federal, national, state, and, where appropriate, tribal contacts for more information. (5/09, reaffirmed 1/13)

EARLY CHILDHOOD ADVERSITY, TOXIC STRESS, AND THE ROLE OF THE PEDIATRICIAN: TRANSLATING DEVELOPMENTAL SCIENCE INTO LIFELONG HEALTH

Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Advances in a wide range of biological, behavioral, and social sciences are expanding our understanding of how early environmental influences (the ecology) and genetic predispositions (the biologic program) affect learning capacities, adaptive behaviors, lifelong physical and mental health, and adult productivity. A supporting technical report from the American Academy of Pediatrics (AAP) presents an integrated ecobiodevelopmental framework to assist in translating these dramatic advances in developmental science into improved health across the life span. Pediatricians are now armed with new information about the adverse effects of toxic stress on brain development, as well as a deeper understanding of the early life origins of many adult diseases. As trusted authorities in child health and development, pediatric providers must now complement the early identification of developmental concerns with a greater focus on those interventions and community investments that reduce external threats to healthy brain growth. To this end, AAP endorses a developing leadership role for the entire pediatric community—one that mobilizes the scientific expertise of both basic and clinical researchers, the family-centered care of the pediatric medical home, and the public influence of AAP and its state chapters—to catalyze fundamental change in early childhood policy and services. AAP is committed to leveraging science to inform the development of innovative strategies to reduce the precipitants of toxic stress in young children and to mitigate their negative effects on the course of development and health across the life span. (12/11)

EARLY CHILDHOOD CARIES IN INDIGENOUS COMMUNITIES

Committee on Native American Child Health (joint with Canadian Paediatric Society First Nations, Inuit, and Métis Committee)

ABSTRACT. The oral health of Indigenous children of Canada (First Nations, Inuit, and Métis) and the United States (American Indian, Alaska Native) is a major child health issue: there is a high prevalence of early childhood caries (ECC) and resulting adverse health effects in this community, as well as high rates and costs of restorative and surgical treatments under general anesthesia. ECC is an infectious disease that is influenced by multiple factors, including socioeconomic determinants, and requires a combination of approaches for improvement. This statement includes recommendations for preventive oral health and clinical care for young infants and pregnant women by primary health care providers, community-based health-promotion initiatives, oral health workforce and access issues, and advocacy for community water fluoridation and fluoride-varnish program access. Further community-based research on the epidemiology, prevention, management, and microbiology of ECC in Indigenous communities would be beneficial. (5/11)

EARLY INTERVENTION, IDEA PART C SERVICES, AND THE MEDICAL HOME: COLLABORATION FOR BEST PRACTICE AND BEST OUTCOMES (CLINICAL REPORT)

Richard C. Adams, MD; Carl Tapia, MD; and Council on Children With Disabilities

ABSTRACT. The medical home and the Individuals With Disabilities Education Act Part C Early Intervention Program share many common purposes for infants and children ages 0 to 3 years, not the least of which is a family-centered focus. Professionals in pediatric medical home practices see substantial numbers of infants and toddlers with developmental delays and/or complex chronic conditions. Economic, health, and family-focused data each underscore the critical role of timely referral for relationship-based, individualized, accessible early intervention services and the need for collaborative partnerships in care. The medical home process and Individuals With Disabilities Education Act Part C policy both support nurturing relationships and family-centered care; both offer clear value in terms of economic and health outcomes. Best practice models for early intervention services incorporate learning in the natural environment and coaching models. Proactive medical homes provide strategies for effective developmental surveillance, family-centered resources, and tools to support high-risk groups, and comanagement of infants with special health care needs, including the monitoring of services provided and outcomes achieved. (9/13)

ECHOCARDIOGRAPHY IN INFANTS AND CHILDREN

Section on Cardiology

ABSTRACT. It is the intent of this statement to inform pediatric providers on the appropriate use of echocardiography. Although on-site consultation may be impossible, methods should be established to ensure timely review of echocardiograms by a pediatric cardiologist. With advances in data transmission, echocardiography information can be exchanged, in some cases eliminating the need for a costly patient transfer. By cooperating through training, education, and referral, complete and cost-effective echocardiographic services can be provided to all children. (6/97, reaffirmed 3/03, 3/07)

EDUCATION OF CHILDREN WITH HUMAN IMMUNODEFICIENCY VIRUS INFECTION

Committee on Pediatric AIDS

ABSTRACT. Treatment for human immunodeficiency virus (HIV) infection has enabled more children and youths to attend school and participate in school activities. Children and youths with HIV infection should receive the same education as those with other chronic illnesses. They may require special services, including home instruction, to provide continuity of education. Confidentiality about HIV infection status should be maintained with parental consent required for disclosure. Youths also should assent or consent as is appropriate for disclosure of their diagnosis. (6/00, reaffirmed 3/03, 10/06, 4/10, 3/13)

EFFECTS OF EARLY NUTRITIONAL INTERVENTIONS ON THE DEVELOPMENT OF ATOPIC DISEASE IN INFANTS AND CHILDREN: THE ROLE OF MATERNAL DIETARY RESTRICTION, BREASTFEEDING, TIMING OF INTRODUCTION OF COMPLEMENTARY FOODS, AND HYDROLYZED FORMULAS (CLINICAL REPORT)

Frank R. Greer, MD; Scott H. Sicherer, MD; A. Wesley Burks, MD; Committee on Nutrition; and Section on Allergy and Immunology

ABSTRACT. This clinical report reviews the nutritional options during pregnancy, lactation, and the first year of life that may affect the development of atopic disease (atopic dermatitis, asthma, food allergy) in early life. It replaces an earlier policy statement from the American Academy of Pediatrics that addressed the use of hypoallergenic infant formulas and included provisional recommendations for dietary management for the prevention of atopic disease. The documented benefits of nutritional intervention that may prevent or delay the onset of atopic disease are largely limited to infants at high risk of developing allergy (ie, infants with at least 1 first-degree relative [parent or sibling] with allergic disease). Current evidence does not support a major role for maternal dietary restrictions during pregnancy or lactation. There is evidence that breastfeeding for at least 4 months, compared with feeding formula made with intact cow milk protein, prevents or delays the occurrence of atopic dermatitis, cow milk allergy, and wheezing in early childhood. In studies of infants at high risk of atopy and who are not exclusively breastfed for 4 to 6 months, there is modest evidence that the onset of atopic disease may be delayed or prevented by the use of hydrolyzed formulas compared with formula made with intact cow milk protein, particularly for atopic dermatitis. Comparative studies of the various hydrolyzed formulas also indicate that not all formulas have the same protective benefit. There is also little evidence that delaying the timing of the introduction of complementary foods beyond 4 to 6 months of age prevents the occurrence of atopic disease. At present, there are insufficient data to document a protective effect of any dietary intervention beyond 4 to 6 months of age for the development of atopic disease. (1/08)

ELECTRONIC PRESCRIBING SYSTEMS IN PEDIATRICS: THE RATIONALE AND FUNCTIONALITY REQUIREMENTS

Council on Clinical Information Technology

ABSTRACT. The use of electronic prescribing applications in pediatric practice, as recommended by the federal government and other national health care improvement organizations, should be encouraged. Legislation and policies that foster adoption of electronic prescribing systems by pediatricians should recognize both specific pediatric requirements and general economic incentives required to speed the adoption of these systems. Continued research into improving the effectiveness of these systems, recognizing the unique challenges of providing care to the pediatric population, should be promoted. (6/07)

ELECTRONIC PRESCRIBING SYSTEMS IN PEDIATRICS: THE RATIONALE AND FUNCTIONALITY REQUIREMENTS (TECHNICAL REPORT)

Robert S. Gerstle, MD; Christoph U. Lehmann, MD; and

Council on Clinical Information Technology

ABSTRACT. This technical report discusses electronic prescribing systems and their limitations and potential benefits, particularly to the pediatrician in the ambulatory setting. In the report we acknowledge the benefits of integrating these systems with electronic health records and practice-management systems and recommend that the adoption of electronic prescribing systems be done in the context of ultimately moving toward an electronic health record. This technical report supports the accompanying American Academy of Pediatrics policy-statement recommendations on the adoption of electronic prescribing systems by pediatricians. (6/07)

ELECTRONIC PRESCRIBING IN PEDIATRICS: TOWARD SAFER AND MORE EFFECTIVE MEDICATION MANAGEMENT

Council on Clinical Information Technology

ABSTRACT. This policy statement identifies the potential value of electronic prescribing (e-prescribing) systems in improving quality and reducing harm in pediatric health care. On the basis of limited but positive pediatric data and on the basis of federal statutes that provide incentives for the use of e-prescribing systems, the American Academy of Pediatrics recommends the adoption of e-prescribing systems with pediatric functionality. The American Academy of Pediatrics also recommends a set of functions that technology vendors should provide when e-prescribing systems are used in environments in which children receive care. (3/13)

ELECTRONIC PRESCRIBING IN PEDIATRICS: TOWARD SAFER AND MORE EFFECTIVE MEDICATION MANAGEMENT (TECHNICAL REPORT)

Kevin B. Johnson, MD, MS; Christoph U. Lehmann, MD; and

Council on Clinical Information Technology

ABSTRACT. This technical report discusses recent advances in electronic prescribing (e-prescribing) systems, including the evidence base supporting their limitations and potential benefits. Specifically, this report acknowledges that there are limited but positive pediatric data supporting the role of e-prescribing in mitigating medication errors, improving communication with dispensing pharmacists, and improving medication adherence. On the basis of these data and on the basis of federal statutes that provide incentives for the use of e-prescribing systems, the American Academy of Pediatrics recommends the adoption of e-prescribing systems with pediatric functionality. This report supports the accompanying policy statement from the American Academy of Pediatrics recommending the adoption of e-prescribing by pediatric health care providers. (3/13)

EMERGENCY CONTRACEPTION

Committee on Adolescence

ABSTRACT. Despite significant declines over the past 2 decades, the United States continues to have teen birth rates that are significantly higher than other industrialized

nations. Use of emergency contraception can reduce the risk of pregnancy if used up to 120 hours after unprotected intercourse or contraceptive failure and is most effective if used in the first 24 hours. Indications for the use of emergency contraception include sexual assault, unprotected intercourse, condom breakage or slippage, and missed or late doses of hormonal contraceptives, including the oral contraceptive pill, contraceptive patch, contraceptive ring (ie, improper placement or loss/expulsion), and injectable contraception. Adolescents younger than 17 years must obtain a prescription from a physician to access emergency contraception in most states. In all states, both males and females 17 years or older can obtain emergency contraception without a prescription. Adolescents are more likely to use emergency contraception if it has been prescribed in advance of need. The aim of this updated policy statement is to (1) educate pediatricians and other physicians on available emergency contraceptive methods; (2) provide current data on safety, efficacy, and use of emergency contraception in teenagers; and (3) encourage routine counseling and advance emergency-contraception prescription as 1 part of a public health strategy to reduce teen pregnancy. This policy focuses on pharmacologic methods of emergency contraception used within 120 hours of unprotected or underprotected coitus for the prevention of unintended pregnancy. Emergency contraceptive medications include products labeled and dedicated for use as emergency contraception by the US Food and Drug Administration (levonorgestrel and ulipristal) and the "off-label" use of combination oral contraceptives. (11/12)

EMERGENCY CONTRACEPTION: ADDENDUM

Committee on Adolescence

This is an addendum to the American Academy of Pediatrics Policy Statement "Emergency Contraception" (Pediatrics. 2012;130(6):1174–1182).

In April 2013, Judge Edward Korman of the US District Court of Eastern New York directed the Food and Drug Administration (FDA) to lift the ban on over-the-counter availability of levonorgestrel-based emergency contraceptives without a prescription and without point-of-sale or age restrictions. In June 2013, the Obama administration withdrew its appeal to the Korman ruling, and the FDA allowed the 1-pill formulation Plan B One-Step (Teva Women's Health Inc, Frazer, PA) to be made available on the shelf without age restriction in the United States. The FDA granted Plan B One-Step 3 years of exclusive rights to sell the product without an age restriction. One-pill generic versions will likely be allowed to be sold on the shelf next to Plan B One-Step, but these products will require age verification and will not be sold to those younger than 17 years without a prescription. The 2-pill formulations of levonorgestrel-based emergency contraceptives will remain behind the pharmacy counter and will also not be sold to those younger than 17 years without a prescription. (2/14)

See full text on page 647.

EMERGENCY INFORMATION FORMS AND EMERGENCY PREPAREDNESS FOR CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Committee on Pediatric Emergency Medicine and Council on Clinical Information Technology (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

ABSTRACT. Children with chronic medical conditions rely on complex management plans for problems that cause them to be at increased risk for suboptimal outcomes in emergency situations. The emergency information form (EIF) is a medical summary that describes medical condition(s), medications, and special health care needs to inform health care providers of a child's special health conditions and needs so that optimal emergency medical care can be provided. This statement describes updates to EIFs, including computerization of the EIF, expanding the potential benefits of the EIF, quality-improvement programs using the EIF, the EIF as a central repository, and facilitating emergency preparedness in disaster management and drills by using the EIF. (3/10, reaffirmed 7/14)

ENDORSEMENT OF HEALTH AND HUMAN SERVICES RECOMMENDATION FOR PULSE OXIMETRY SCREENING FOR CRITICAL CONGENITAL HEART DISEASE

Section on Cardiology and Cardiac Surgery Executive Committee

ABSTRACT. Incorporation of pulse oximetry to the assessment of the newborn infant can enhance detection of critical congenital heart disease (CCHD). Recently, the Secretary of Health and Human Services (HHS) recommended that screening for CCHD be added to the uniform screening panel. The American Academy of Pediatrics (AAP) has been a strong advocate of early detection of CCHD and fully supports the decision of the Secretary of HHS.

The AAP has published strategies for the implementation of pulse oximetry screening, which addressed critical issues such as necessary equipment, personnel, and training, and also provided specific recommendations for assessment of saturation by using pulse oximetry as well as appropriate management of a positive screening result. The AAP is committed to the safe and effective implementation of pulse oximetry screening and is working with other advocacy groups and governmental agencies to promote pulse oximetry and to support widespread surveillance for CCHD.

Going forward, AAP chapters will partner with state health departments to implement the new screening strategy for CCHD and will work to ensure that there is an adequate system for referral for echocardiographic/pediatric cardiac evaluation after a positive screening result. It is imperative that AAP members engage their respective policy makers in adopting and funding the recommendations made by the Secretary of HHS. (12/11)

ENHANCING PEDIATRIC WORKFORCE DIVERSITY AND PROVIDING CULTURALLY EFFECTIVE PEDIATRIC CARE: IMPLICATIONS FOR PRACTICE, EDUCATION, AND POLICY MAKING

Committee on Pediatric Workforce

ABSTRACT. This policy statement serves to combine and update 2 previously independent but overlapping state-

ments from the American Academy of Pediatrics (AAP) on culturally effective health care (CEHC) and workforce diversity. The AAP has long recognized that with the ever-increasing diversity of the pediatric population in the United States, the health of all children depends on the ability of all pediatricians to practice culturally effective care. CEHC can be defined as the delivery of care within the context of appropriate physician knowledge, understanding, and appreciation of all cultural distinctions, leading to optimal health outcomes. The AAP believes that CEHC is a critical social value and that the knowledge and skills necessary for providing CEHC can be taught and acquired through focused curricula across the spectrum of lifelong learning.

This statement also addresses workforce diversity, health disparities, and affirmative action. The discussion of diversity is broadened to include not only race, ethnicity, and language but also cultural attributes such as gender, religious beliefs, sexual orientation, and disability, which may affect the quality of health care. The AAP believes that efforts must be supported through health policy and advocacy initiatives to promote the delivery of CEHC and to overcome educational, organizational, and other barriers to improving workforce diversity. (9/13)

EPIDEMIOLOGY AND DIAGNOSIS OF HEALTH CARE-ASSOCIATED INFECTIONS IN THE NICU (TECHNICAL REPORT)

Committee on Fetus and Newborn and Committee on Infectious Diseases

ABSTRACT. Health care-associated infections in the NICU are a major clinical problem resulting in increased morbidity and mortality, prolonged length of hospital stays, and increased medical costs. Neonates are at high risk for health care-associated infections because of impaired host defense mechanisms, limited amounts of protective endogenous flora on skin and mucosal surfaces at time of birth, reduced barrier function of neonatal skin, the use of invasive procedures and devices, and frequent exposure to broad-spectrum antibiotics. This statement will review the epidemiology and diagnosis of health care-associated infections in newborn infants. (3/12)

EQUIPMENT FOR GROUND AMBULANCES

American Academy of Pediatrics (joint with American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and National Association of State EMS Officials)

On January 1, 2014, the American Academy of Pediatrics, American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and National Association of State EMS Officials coauthored a joint policy statement, "Equipment for Ground Ambulances" (*Prehosp Emerg Care.* 2014;19[1]:92-97). The full text of the joint policy statement is available at: <http://informahealthcare.com/doi/full/10.3109/10903127.2013.851312>. Copyright © 2014 Informa Plc. (8/14)

ESSENTIAL CONTRACTUAL LANGUAGE FOR MEDICAL NECESSITY IN CHILDREN

Committee on Child Health Financing

ABSTRACT. The previous policy statement from the American Academy of Pediatrics, "Model Language for Medical Necessity in Children," was published in July 2005. Since that time, there have been new and emerging delivery and payment models. The relationship established between health care providers and health plans should promote arrangements that are beneficial to all who are affected by these contractual arrangements. Pediatricians play an important role in ensuring that the needs of children are addressed in these emerging systems. It is important to recognize that health care plans designed for adults may not meet the needs of children. Language in health care contracts should reflect the health care needs of children and families. Informed pediatricians can make a difference in the care of children and influence the role of primary care physicians in the new paradigms. This policy highlights many of the important elements pediatricians should assess as providers develop a role in emerging care models. (7/13)

ETHICAL AND POLICY ISSUES IN GENETIC TESTING AND SCREENING OF CHILDREN

Committee on Bioethics and Committee on Genetics (joint with American College of Medical Genetics and Genomics)

ABSTRACT. The genetic testing and genetic screening of children are commonplace. Decisions about whether to offer genetic testing and screening should be driven by the best interest of the child. The growing literature on the psychosocial and clinical effects of such testing and screening can help inform best practices. This policy statement represents recommendations developed collaboratively by the American Academy of Pediatrics and the American College of Medical Genetics and Genomics with respect to many of the scenarios in which genetic testing and screening can occur. (2/13)

ETHICAL CONSIDERATIONS IN RESEARCH WITH SOCIALLY IDENTIFIABLE POPULATIONS

Committee on Native American Child Health and Committee on Community Health Services

ABSTRACT. Community-based research raises ethical issues not normally encountered in research conducted in academic settings. In particular, conventional risk-benefits assessments frequently fail to recognize harms that can occur in socially identifiable populations as a result of research participation. Furthermore, many such communities require more stringent measures of beneficence that must be applied directly to the participating communities. In this statement, the American Academy of Pediatrics sets forth recommendations for minimizing harms that may result from community-based research by emphasizing community involvement in the research process. (1/04, reaffirmed 10/07, 1/13)

ETHICAL CONTROVERSIES IN ORGAN DONATION AFTER CIRCULATORY DEATH

Committee on Bioethics

ABSTRACT. The persistent mismatch between the supply of and need for transplantable organs has led to efforts to increase the supply, including controlled donation after

circulatory death (DCD). Controlled DCD involves organ recovery after the planned withdrawal of life-sustaining treatment and the declaration of death according to the cardiorespiratory criteria. Two central ethical issues in DCD are when organ recovery can begin and how to manage conflicts of interests. The "dead donor rule" should be maintained, and donors in cases of DCD should only be declared dead after the permanent cessation of circulatory function. Permanence is generally established by a 2- to 5-minute waiting period. Given ongoing controversy over whether the cessation must also be irreversible, physicians should not be required to participate in DCD. Because the preparation for organ recovery in DCD begins before the declaration of death, there are potential conflicts between the donor's and recipient's interests. These conflicts can be managed in a variety of ways, including informed consent and separating the various participants' roles. For example, informed consent should be sought for pre-mortem interventions to improve organ viability, and organ procurement organization personnel and members of the transplant team should not be involved in the discontinuation of life-sustaining treatment or the declaration of death. It is also important to emphasize that potential donors in cases of DCD should receive integrated interdisciplinary palliative care, including sedation and analgesia. (4/13)

ETHICAL ISSUES WITH GENETIC TESTING IN PEDIATRICS

Committee on Bioethics

ABSTRACT. Advances in genetic research promise great strides in the diagnosis and treatment of many childhood diseases. However, emerging genetic technology often enables testing and screening before the development of definitive treatment or preventive measures. In these circumstances, careful consideration must be given to testing and screening of children to ensure that use of this technology promotes the best interest of the child. This statement reviews considerations for the use of genetic technology for newborn screening, carrier testing, and testing for susceptibility to late-onset conditions. Recommendations are made promoting informed participation by parents for newborn screening and limited use of carrier testing and testing for late-onset conditions in the pediatric population. Additional research and education in this developing area of medicine are encouraged. (6/01, reaffirmed 1/05, 1/09)

ETHICS AND THE CARE OF CRITICALLY ILL INFANTS AND CHILDREN

Committee on Bioethics

ABSTRACT. The ability to provide life support to ill children who, not long ago, would have died despite medicine's best efforts challenges pediatricians and families to address profound moral questions. Our society has been divided about extending the life of some patients, especially newborns and older infants with severe disabilities. The American Academy of Pediatrics (AAP) supports individualized decision making about life-sustaining medical treatment for all children, regardless of age. These decisions should be jointly made by physicians and parents, unless good reasons require invoking estab-

lished child protective services to contravene parental authority. At this time, resource allocation (rationing) decisions about which children should receive intensive care resources should be made clear and explicit in public policy, rather than be made at the bedside. (7/96, reaffirmed 10/99, 6/03)

EVALUATING CHILDREN WITH FRACTURES FOR CHILD PHYSICAL ABUSE (CLINICAL REPORT)

Emalee G. Flaherty, MD; Jeannette M. Perez-Rossello, MD; Michael A. Levine, MD; William L. Hennrikus, MD; Committee on Child Abuse and Neglect; Section on Radiology; Section on Endocrinology; and Section on Orthopaedics (joint with Society for Pediatric Radiology)

Fractures are common injuries caused by child abuse. Although the consequences of failing to diagnose an abusive injury in a child can be grave, incorrectly diagnosing child abuse in a child whose fractures have another etiology can be distressing for a family. The aim of this report is to review recent advances in the understanding of fracture specificity, the mechanism of fractures, and other medical diseases that predispose to fractures in infants and children. This clinical report will aid physicians in developing an evidence-based differential diagnosis and performing the appropriate evaluation when assessing a child with fractures. (1/14)

See full text on page 655.

EVALUATING FOR SUSPECTED CHILD ABUSE: CONDITIONS THAT PREDISPOSE TO BLEEDING (TECHNICAL REPORT)

Shannon L. Carpenter, MD, MS; Thomas C. Abshire, MD; James D. Anderst, MD, MS; Section on Hematology/Oncology; and Committee on Child Abuse and Neglect

ABSTRACT. Child abuse might be suspected when children present with cutaneous bruising, intracranial hemorrhage, or other manifestations of bleeding. In these cases, it is necessary to consider medical conditions that predispose to easy bleeding/bruising. When evaluating for the possibility of bleeding disorders and other conditions that predispose to hemorrhage, the pediatrician must consider the child's presenting history, medical history, and physical examination findings before initiating a laboratory investigation. Many medical conditions can predispose to easy bleeding. Before ordering laboratory tests for a disease, it is useful to understand the biochemical basis and clinical presentation of the disorder, condition prevalence, and test characteristics. This technical report reviews the major medical conditions that predispose to bruising/bleeding and should be considered when evaluating for abusive injury. (3/13)

EVALUATING INFANTS AND YOUNG CHILDREN WITH MULTIPLE FRACTURES (CLINICAL REPORT)

Carole Jenny, MD, MBA, FAAP, for Committee on Child Abuse and Neglect

ABSTRACT. Infants and toddlers with multiple unexplained fractures are often victims of inflicted injury. However, several medical conditions can also cause multiple fractures in children in this age group. In this report, the differential diagnosis of multiple fractures is presented, and diagnostic testing available to the clinician is discussed. The hypothetical entity "temporary brittle-bone

disease" is examined also. Although frequently offered in court cases as a cause of multiple infant fractures, there is no evidence that this condition actually exists. (9/06)

EVALUATION AND MANAGEMENT OF THE INFANT EXPOSED TO HIV-1 IN THE UNITED STATES (CLINICAL REPORT)

Peter L. Havens, MD; Lynne M. Mofenson, MD; and Committee on Pediatric AIDS

ABSTRACT. The pediatrician plays a key role in the prevention of mother-to-child transmission of HIV-1 infection. For infants born to women with HIV-1 infection identified during pregnancy, the pediatrician ensures that antiretroviral prophylaxis is provided to the infant to decrease the risk of acquiring HIV-1 infection and promotes avoidance of postnatal HIV-1 transmission by advising HIV-1-infected women not to breastfeed. The pediatrician should perform HIV-1 antibody testing for infants born to women whose HIV-1 infection status was not determined during pregnancy or labor. For HIV-1-exposed infants, the pediatrician monitors the infant for early determination of HIV-1 infection status and for possible short- and long-term toxicity from antiretroviral exposures. Provision of chemoprophylaxis for *Pneumocystis jiroveci* pneumonia and support of families living with HIV-1 by providing counseling to parents or caregivers are also important components of care. (12/08)

EVALUATION FOR BLEEDING DISORDERS IN SUSPECTED CHILD ABUSE (CLINICAL REPORT)

James D. Anderst, MD, MS; Shannon L. Carpenter, MD, MS; Thomas C. Abshire, MD; Section on Hematology/Oncology; and Committee on Child Abuse and Neglect

ABSTRACT. Bruising or bleeding in a child can raise the concern for child abuse. Assessing whether the findings are the result of trauma and/or whether the child has a bleeding disorder is critical. Many bleeding disorders are rare, and not every child with bruising/bleeding concerning for abuse requires an evaluation for bleeding disorders. In some instances, however, bleeding disorders can present in a manner similar to child abuse. The history and clinical evaluation can be used to determine the necessity of an evaluation for a possible bleeding disorder, and prevalence and known clinical presentations of individual bleeding disorders can be used to guide the extent of the laboratory testing. This clinical report provides guidance to pediatricians and other clinicians regarding the evaluation for bleeding disorders when child abuse is suspected. (3/13)

THE EVALUATION OF CHILDREN IN THE PRIMARY CARE SETTING WHEN SEXUAL ABUSE IS SUSPECTED (CLINICAL REPORT)

Carole Jenny, MD, MBA; James E. Crawford-Jakubiak, MD; and Committee on Child Abuse and Neglect

ABSTRACT. This clinical report updates a 2005 report from the American Academy of Pediatrics on the evaluation of sexual abuse in children. The medical assessment of suspected child sexual abuse should include obtaining a history, performing a physical examination, and obtaining appropriate laboratory tests. The role of the physician includes determining the need to report suspected sexual abuse; assessing the physical, emotional, and behavioral

consequences of sexual abuse; providing information to parents about how to support their child; and coordinating with other professionals to provide comprehensive treatment and follow-up of children exposed to child sexual abuse. (7/13)

THE EVALUATION OF SEXUAL BEHAVIORS IN CHILDREN (CLINICAL REPORT)

Nancy D. Kellogg, MD, and Committee on Child Abuse and Neglect

ABSTRACT. Most children will engage in sexual behaviors at some time during childhood. These behaviors may be normal but can be confusing and concerning to parents or disruptive or intrusive to others. Knowledge of age-appropriate sexual behaviors that vary with situational and environmental factors can assist the clinician in differentiating normal sexual behaviors from sexual behavior problems. Most situations that involve sexual behaviors in young children do not require child protective services intervention; for behaviors that are age-appropriate and transient, the pediatrician may provide guidance in supervision and monitoring of the behavior. If the behavior is intrusive, hurtful, and/or age-inappropriate, a more comprehensive assessment is warranted. Some children with sexual behavior problems may reside or have resided in homes characterized by inconsistent parenting, violence, abuse, or neglect and may require more immediate intervention and referrals. (8/09, reaffirmed 3/13)

EVALUATION OF SUSPECTED CHILD PHYSICAL ABUSE (CLINICAL REPORT)

Nancy D. Kellogg, MD, and Committee on Child Abuse and Neglect

ABSTRACT. This report provides guidance in the clinical approach to the evaluation of suspected physical abuse in children. The medical assessment is outlined with respect to obtaining a history, physical examination, and appropriate ancillary testing. The role of the physician may encompass reporting suspected abuse; assessing the consistency of the explanation, the child's developmental capabilities, and the characteristics of the injury or injuries; and coordination with other professionals to provide immediate and long-term treatment and follow-up for victims. Accurate and timely diagnosis of children who are suspected victims of abuse can ensure appropriate evaluation, investigation, and outcomes for these children and their families. (6/07, reaffirmed 5/12)

EVIDENCE FOR THE DIAGNOSIS AND TREATMENT OF ACUTE UNCOMPLICATED SINUSITIS IN CHILDREN: A SYSTEMATIC REVIEW (TECHNICAL REPORT)

Michael J. Smith, MD, MSCE

In 2001, the American Academy of Pediatrics published clinical practice guidelines for the management of acute bacterial sinusitis (ABS) in children. The technical report accompanying those guidelines included 21 studies that assessed the diagnosis and management of ABS in children. This update to that report incorporates studies of pediatric ABS that have been performed since 2001. Overall, 17 randomized controlled trials of the treatment of sinusitis in children were identified and analyzed. Four randomized, double-blind, placebo-controlled trials of antimicrobial therapy have been published. The results

of these studies varied, likely due to differences in inclusion and exclusion criteria. Because of this heterogeneity, formal meta-analyses were not performed. However, qualitative analysis of these studies suggests that children with greater severity of illness at presentation are more likely to benefit from antimicrobial therapy. An additional 5 trials compared different antimicrobial therapies but did not include placebo groups. Six trials assessed a variety of ancillary treatments for ABS in children, and 3 focused on subacute sinusitis. Although the number of pediatric trials has increased since 2001, there are still limited data to guide the diagnosis and management of ABS in children. Diagnostic and treatment guidelines focusing on severity of illness at the time of presentation have the potential to identify those children most likely to benefit from antimicrobial therapy and at the same time minimize unnecessary use of antibiotics. (6/13)

AN EVIDENCE-BASED REVIEW OF IMPORTANT ISSUES CONCERNING NEONATAL HYPERBILIRUBINEMIA (TECHNICAL REPORT)

Stanley Ip, MD; Mei Chung, MPH; John Kulig, MD, MPH; Rebecca O'Brien, MD; Robert Sege, MD, PhD; Stephan Glick, MD; M. Jeffrey Maisels, MB, BCH; Joseph Lau, MD; Steering Committee on Quality and Improvement; and Subcommittee on Hyperbilirubinemia

ABSTRACT. This article is adapted from a published evidence report concerning neonatal hyperbilirubinemia with an added section on the risk of blood exchange transfusion (BET). Based on a summary of multiple case reports that spanned more than 30 years, we conclude that kernicterus, although infrequent, has at least 10% mortality and at least 70% long-term morbidity. It is evident that the preponderance of kernicterus cases occurred in infants with a bilirubin level higher than 20 mg/dL. Given the diversity of conclusions on the relationship between peak bilirubin levels and behavioral and neurodevelopmental outcomes, it is apparent that the use of a single total serum bilirubin level to predict long-term outcomes is inadequate and will lead to conflicting results. Evidence for efficacy of treatments for neonatal hyperbilirubinemia was limited. Overall, the 4 qualifying studies showed that phototherapy had an absolute risk-reduction rate of 10% to 17% for prevention of serum bilirubin levels higher than 20 mg/dL in healthy infants with jaundice. There is no evidence to suggest that phototherapy for neonatal hyperbilirubinemia has any long-term adverse neurodevelopmental effects. Transcutaneous measurements of bilirubin have a linear correlation to total serum bilirubin and may be useful as screening devices to detect clinically significant jaundice and decrease the need for serum bilirubin determinations. Based on our review of the risks associated with BETs from 15 studies consisting mainly of infants born before 1970, we conclude that the mortality within 6 hours of BET ranged from 3 per 1000 to 4 per 1000 exchanged infants who were term and without serious hemolytic diseases. Regardless of the definitions and rates of BET-associated morbidity and the various pre-exchange clinical states of the exchanged infants, in many cases the morbidity was minor (eg, postexchange anemia). Based on the results from the most recent study to report BET morbidity, the overall risk of permanent

sequelae in 25 sick infants who survived BET was from 5% to 10%. (7/04)

EXCESSIVE SLEEPINESS IN ADOLESCENTS AND YOUNG ADULTS: CAUSES, CONSEQUENCES, AND TREATMENT STRATEGIES (TECHNICAL REPORT)

Richard P. Millman, MD; Working Group on Sleepiness in

Adolescents/Young Adults; and Committee on Adolescence
ABSTRACT. Adolescents and young adults are often excessively sleepy. This excessive sleepiness can have a profound negative effect on school performance, cognitive function, and mood and has been associated with other serious consequences such as increased incidence of automobile crashes. In this article we review available scientific knowledge about normal sleep changes in adolescents (13–22 years of age), the factors associated with chronic insufficient sleep, the effect of insufficient sleep on a variety of systems and functions, and the primary sleep disorders or organic dysfunctions that, if untreated, can cause excessive daytime sleepiness in this population. (6/05)

EXPERT WITNESS PARTICIPATION IN CIVIL AND CRIMINAL PROCEEDINGS

Committee on Medical Liability and Risk Management

ABSTRACT. The interests of the public and both the medical and legal professions are best served when scientifically sound and unbiased expert witness testimony is readily available in civil and criminal proceedings. As members of the medical community, patient advocates, and private citizens, pediatricians have ethical and professional obligations to assist in the administration of justice. The American Academy of Pediatrics believes that the adoption of the recommendations outlined in this statement will improve the quality of medical expert witness testimony in legal proceedings and, thereby, increase the probability of achieving outcomes that are fair, honest, and equitable. Strategies for enforcing guidance and promoting oversight of expert witnesses are proposed. (6/09)

EXPOSURE TO NONTRADITIONAL PETS AT HOME AND TO ANIMALS IN PUBLIC SETTINGS: RISKS TO CHILDREN (CLINICAL REPORT)

Larry K. Pickering, MD; Nina Marano, DVM, MPH; Joseph A. Bocchini, MD; Frederick J. Angulo, DVM, PhD; and Committee on Infectious Diseases

ABSTRACT. Exposure to animals can provide many benefits during the growth and development of children. However, there are potential risks associated with animal exposures, including exposure to nontraditional pets in the home and animals in public settings. Educational materials, regulations, and guidelines have been developed to minimize these risks. Pediatricians, veterinarians, and other health care professionals can provide advice on selection of appropriate pets as well as prevention of disease transmission from nontraditional pets and when children contact animals in public settings. (10/08, reaffirmed 12/11)

EYE EXAMINATION IN INFANTS, CHILDREN, AND YOUNG ADULTS BY PEDIATRICIANS

Committee on Practice and Ambulatory Medicine and Section on Ophthalmology (joint with American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology)

ABSTRACT. Early detection and prompt treatment of ocular disorders in children is important to avoid lifelong visual impairment. Examination of the eyes should be performed beginning in the newborn period and at all well-child visits. Newborns should be examined for ocular structural abnormalities, such as cataract, corneal opacity, and ptosis, which are known to result in visual problems. Vision assessment beginning at birth has been endorsed by the American Academy of Pediatrics, the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology. All children who are found to have an ocular abnormality or who fail vision assessment should be referred to a pediatric ophthalmologist or an eye care specialist appropriately trained to treat pediatric patients. (4/03, reaffirmed 5/07)

THE EYE EXAMINATION IN THE EVALUATION OF CHILD ABUSE (CLINICAL REPORT)

Alex V. Levin, MD, MHSc; Cindy W. Christian, MD; Committee on Child Abuse and Neglect; and Section on Ophthalmology

ABSTRACT. Retinal hemorrhage is an important indicator of possible abusive head trauma, but it is also found in a number of other conditions. Distinguishing the type, number, and pattern of retinal hemorrhages may be helpful in establishing a differential diagnosis. Identification of ocular abnormalities requires a full retinal examination by an ophthalmologist using indirect ophthalmoscopy through a pupil that has been pharmacologically dilated. At autopsy, removal of the eyes and orbital tissues may also reveal abnormalities not discovered before death. In previously well young children who experience unexpected apparent life-threatening events with no obvious cause, children with head trauma that results in significant intracranial hemorrhage and brain injury, victims of abusive head trauma, and children with unexplained death, premortem clinical eye examination and postmortem examination of the eyes and orbits may be helpful in detecting abnormalities that can help establish the underlying etiology. (7/10)

FACILITIES AND EQUIPMENT FOR THE CARE OF PEDIATRIC PATIENTS IN A COMMUNITY HOSPITAL (CLINICAL REPORT)

Committee on Hospital Care

ABSTRACT. Many children who require hospitalization are admitted to community hospitals that are more accessible for families and their primary care physicians but vary substantially in their pediatric resources. The intent of this clinical report is to provide basic guidelines for furnishing and equipping a pediatric area in a community hospital. (5/03, reaffirmed 5/07, 8/13)

FAILURE TO THRIVE AS A MANIFESTATION OF CHILD NEGLECT (CLINICAL REPORT)

Robert W. Block, MD; Nancy F. Krebs, MD; Committee on

Child Abuse and Neglect; and Committee on Nutrition

ABSTRACT. Failure to thrive is a common problem in infancy and childhood. It is most often multifactorial in origin. Inadequate nutrition and disturbed social interactions contribute to poor weight gain, delayed development, and abnormal behavior. The syndrome develops in a significant number of children as a consequence of child neglect. This clinical report is intended to focus the pediatrician on the consideration, evaluation, and management of failure to thrive when child neglect may be present. Child protective services agencies should be notified when the evaluation leads to a suspicion of abuse or neglect. (11/05, reaffirmed 1/09)

FALLS FROM HEIGHTS: WINDOWS, ROOFS, AND BALCONIES

Committee on Injury and Poison Prevention

ABSTRACT. Falls of all kinds represent an important cause of child injury and death. In the United States, approximately 140 deaths from falls occur annually in children younger than 15 years. Three million children require emergency department care for fall-related injuries. This policy statement examines the epidemiology of falls from heights and recommends preventive strategies for pediatricians and other child health care professionals. Such strategies involve parent counseling, community programs, building code changes, legislation, and environmental modification, such as the installation of window guards and balcony railings. (5/01, reaffirmed 10/04, 5/07, 6/10)

FAMILIES AND ADOPTION: THE PEDIATRICIAN'S ROLE IN SUPPORTING COMMUNICATION (CLINICAL REPORT)

Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. Each year, more children join families through adoption. Pediatricians have an important role in assisting adoptive families in the various challenges they may face with respect to adoption. The acceptance of the differences between families formed through birth and those formed through adoption is essential in promoting positive emotional growth within the family. It is important for pediatricians to be informed about adoption and to share this knowledge with adoptive families. Parents need ongoing advice with respect to adoption issues and need to be supported in their communication with their adopted children. (12/03)

FATHERS AND PEDIATRICIANS: ENHANCING MEN'S ROLES IN THE CARE AND DEVELOPMENT OF THEIR CHILDREN (CLINICAL REPORT)

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Research substantiates that fathers' interactions with their children can exert a positive influence on their children's development. This report suggests ways pediatricians can enhance fathers' caregiving involvement by offering specific, culturally sensitive advice and how pediatricians might change their office practices to

support and increase fathers' active involvement in their children's care and development. (5/04, reaffirmed 8/13)

FEVER AND ANTIPYRETIC USE IN CHILDREN (CLINICAL REPORT)

Janice E. Sullivan, MD; Henry C. Farrar, MD; Section on Clinical Pharmacology and Therapeutics; and Committee on Drugs

ABSTRACT. Fever in a child is one of the most common clinical symptoms managed by pediatricians and other health care providers and a frequent cause of parental concern. Many parents administer antipyretics even when there is minimal or no fever, because they are concerned that the child must maintain a "normal" temperature. Fever, however, is not the primary illness but is a physiologic mechanism that has beneficial effects in fighting infection. There is no evidence that fever itself worsens the course of an illness or that it causes long-term neurologic complications. Thus, the primary goal of treating the febrile child should be to improve the child's overall comfort rather than focus on the normalization of body temperature. When counseling the parents or caregivers of a febrile child, the general well-being of the child, the importance of monitoring activity, observing for signs of serious illness, encouraging appropriate fluid intake, and the safe storage of antipyretics should be emphasized. Current evidence suggests that there is no substantial difference in the safety and effectiveness of acetaminophen and ibuprofen in the care of a generally healthy child with fever. There is evidence that combining these 2 products is more effective than the use of a single agent alone; however, there are concerns that combined treatment may be more complicated and contribute to the unsafe use of these drugs. Pediatricians should also promote patient safety by advocating for simplified formulations, dosing instructions, and dosing devices. (2/11)

FINANCING GRADUATE MEDICAL EDUCATION TO MEET THE NEEDS OF CHILDREN AND THE FUTURE PEDIATRICIAN WORKFORCE

Committee on Pediatric Workforce

ABSTRACT. This policy statement articulates the positions of the American Academy of Pediatrics on graduate medical education and the associated costs and funding mechanisms. It reaffirms the policy of the American Academy of Pediatrics that graduate medical education is a public good and is an essential part of maintaining a high-quality physician workforce. The American Academy of Pediatrics advocates for lifelong learning across the continuum of medical education. This policy statement focuses on the financing of one component of this continuum, namely residency education. The statement calls on federal and state governments to continue their support of residency education and advocates for stable means of funding such as the establishment of an all-payer graduate medical education trust fund. It further proposes a portable authorization system that would allocate graduate medical education funds for direct medical education costs to accredited residency programs on the basis of the selection of the program by qualified student or residents. This system allows the funding to follow the residents to their program. Recognizing the critical

workforce needs of many pediatric medical subspecialties, pediatric surgical specialties, and other pediatric specialty disciplines, this statement maintains that subspecialty fellowship training and general pediatrics research fellowship training should receive adequate support from the graduate medical education financing system, including funding from the National Institutes of Health and other federal agencies, as appropriate. Furthermore, residency education that is provided in freestanding children's hospitals should receive a level of support equivalent to that of other teaching hospitals. The financing of graduate medical education is an important and effective tool to ensure that the future pediatrician workforce can provide optimal health care for infants, children, adolescents, and young adults. (4/08, reaffirmed 1/12)

FINANCING OF PEDIATRIC HOME HEALTH CARE

Committee on Child Health Financing and Section on Home Care

ABSTRACT. In certain situations, home health care has been shown to be a cost-effective alternative to inpatient hospital care. National health expenditures reveal that pediatric home health costs totaled \$5.3 billion in 2000. Medicaid is the major payer for pediatric home health care (77%), followed by other public sources (22%). Private health insurance and families each paid less than 1% of pediatric home health expenses. The most important factors affecting access to home health care are the inadequate supply of clinicians and ancillary personnel, shortages of home health nurses with pediatric expertise, inadequate payment, and restrictive insurance and managed care policies. Many children must stay in the NICU, PICU, and other pediatric wards and intermediate care areas at a much higher cost because of inadequate pediatric home health care services. The main financing problem pertaining to Medicaid is low payment to home health agencies at rates that are insufficient to provide beneficiaries access to home health services. Although home care services may be a covered benefit under private health plans, most do not cover private-duty nursing (83%), home health aides (45%), or home physical, occupational, or speech therapy (33%) and/or impose visit or monetary limits or caps. To advocate for improvements in financing of pediatric home health care, the American Academy of Pediatrics has developed several recommendations for public policy makers, federal and state Medicaid offices, private insurers, managed care plans, Title V officials, and home health care professionals. These recommendations will improve licensing, payment, coverage, and research related to pediatric home health services. (8/06)

FIREARM-RELATED INJURIES AFFECTING THE PEDIATRIC POPULATION

*Council on Injury, Violence, and Poison Prevention
Executive Committee*

ABSTRACT. The absence of guns from children's homes and communities is the most reliable and effective measure to prevent firearm-related injuries in children and adolescents. Adolescent suicide risk is strongly associated with firearm availability. Safe gun storage (guns unloaded and locked, ammunition locked separately) reduces chil-

dren's risk of injury. Physician counseling of parents about firearm safety appears to be effective, but firearm safety education programs directed at children are ineffective. The American Academy of Pediatrics continues to support a number of specific measures to reduce the destructive effects of guns in the lives of children and adolescents, including the regulation of the manufacture, sale, purchase, ownership, and use of firearms; a ban on semiautomatic assault weapons; and the strongest possible regulations of handguns for civilian use. (10/12)

FIREWORKS-RELATED INJURIES TO CHILDREN

Committee on Injury and Poison Prevention

ABSTRACT. An estimated 8500 individuals, approximately 45% of them children younger than 15 years, were treated in US hospital emergency departments during 1999 for fireworks-related injuries. The hands (40%), eyes (20%), and head and face (20%) are the body areas most often involved. Approximately one third of eye injuries from fireworks result in permanent blindness. During 1999, 16 people died as a result of injuries associated with fireworks. Every type of legally available consumer (so-called "safe and sane") firework has been associated with serious injury or death. In 1997, 20 100 fires were caused by fireworks, resulting in \$22.7 million in direct property damage. Fireworks typically cause more fires in the United States on the Fourth of July than all other causes of fire combined on that day. Pediatricians should educate parents, children, community leaders, and others about the dangers of fireworks. Fireworks for individual private use should be banned. Children and their families should be encouraged to enjoy fireworks at public fireworks displays conducted by professionals rather than purchase fireworks for home or private use. (7/01, reaffirmed 1/05, 2/08, 10/11)

FLUORIDE USE IN CARIES PREVENTION IN THE PRIMARY CARE SETTING (CLINICAL REPORT)

Melinda B. Clark, MD, FAAP; Rebecca L. Slayton, DDS, PhD; and Section on Oral Health

ABSTRACT. Dental caries remains the most common chronic disease of childhood in the United States. Caries is a largely preventable condition, and fluoride has proven effectiveness in the prevention of caries. The goals of this clinical report are to clarify the use of available fluoride modalities for caries prevention in the primary care setting and to assist pediatricians in using fluoride to achieve maximum protection against dental caries while minimizing the likelihood of enamel fluorosis. (8/14)

See full text on page 671.

FOLIC ACID FOR THE PREVENTION OF NEURAL TUBE DEFECTS

Committee on Genetics

ABSTRACT. The American Academy of Pediatrics endorses the US Public Health Service (USPHS) recommendation that all women capable of becoming pregnant consume 400 µg of folic acid daily to prevent neural tube defects (NTDs). Studies have demonstrated that periconceptional folic acid supplementation can prevent 50% or more of NTDs such as spina bifida and anencephaly. For

women who have previously had an NTD-affected pregnancy, the Centers for Disease Control and Prevention (CDC) recommends increasing the intake of folic acid to 4000 µg per day beginning at least 1 month before conception and continuing through the first trimester. Implementation of these recommendations is essential for the primary prevention of these serious and disabling birth defects. Because fewer than 1 in 3 women consume the amount of folic acid recommended by the USPHS, the Academy notes that the prevention of NTDs depends on an urgent and effective campaign to close this prevention gap. (8/99, reaffirmed 11/02, 1/07, 5/12)

FOLLOW-UP MANAGEMENT OF CHILDREN WITH TYMPANOSTOMY TUBES

Section on Otolaryngology and Bronchoesophagology

ABSTRACT. The follow-up care of children in whom tympanostomy tubes have been placed is shared by the pediatrician and the otolaryngologist. Guidelines are provided for routine follow-up evaluation, perioperative hearing assessment, and the identification of specific conditions and complications that warrant urgent otolaryngologic consultation. These guidelines have been developed by a consensus of expert opinions. (2/02)

FORGOING LIFE-SUSTAINING MEDICAL TREATMENT IN ABUSED CHILDREN

Committee on Child Abuse and Neglect and Committee on Bioethics

ABSTRACT. A decision to forgo life-sustaining medical treatment (LSMT) for a critically ill child injured as the result of abuse should be made using the same criteria as those used for any critically ill child. The parent or guardian of an abused child may have a conflict of interest when a decision to forgo LSMT risks changing the legal charge faced by a parent, guardian, relative, or acquaintance from assault to manslaughter or homicide. If a physician suspects that a parent or guardian is not acting in a child's best interest, further review and consultation should be sought in hopes of resolving the conflict. A guardian ad litem who will represent the child's interests regarding LSMT should be appointed in all cases in which a parent or guardian may have a conflict of interest. (11/00, reaffirmed 6/03, 10/06, 4/09)

FORGOING MEDICALLY PROVIDED NUTRITION AND HYDRATION IN CHILDREN (CLINICAL REPORT)

Douglas S. Diekema, MD, MPH; Jeffrey R. Botkin, MD, MPH; and Committee on Bioethics

ABSTRACT. There is broad consensus that withholding or withdrawing medical interventions is morally permissible when requested by competent patients or, in the case of patients without decision-making capacity, when the interventions no longer confer a benefit to the patient or when the burdens associated with the interventions outweigh the benefits received. The withdrawal or withholding of measures such as attempted resuscitation, ventilators, and critical care medications is common in the terminal care of adults and children. In the case of adults, a consensus has emerged in law and ethics that the medical administration of fluid and nutrition is not funda-

mentally different from other medical interventions such as use of ventilators; therefore, it can be forgone or withdrawn when a competent adult or legally authorized surrogate requests withdrawal or when the intervention no longer provides a net benefit to the patient. In pediatrics, forgoing or withdrawing medically administered fluids and nutrition has been more controversial because of the inability of children to make autonomous decisions and the emotional power of feeding as a basic element of the care of children. This statement reviews the medical, ethical, and legal issues relevant to the withholding or withdrawing of medically provided fluids and nutrition in children. The American Academy of Pediatrics concludes that the withdrawal of medically administered fluids and nutrition for pediatric patients is ethically acceptable in limited circumstances. Ethics consultation is strongly recommended when particularly difficult or controversial decisions are being considered. (7/09, reaffirmed 1/14)

THE FUTURE OF PEDIATRICS: MENTAL HEALTH COMPETENCIES FOR PEDIATRIC PRIMARY CARE

Committee on Psychosocial Aspects of Child and Family Health and Task Force on Mental Health

ABSTRACT. Pediatric primary care clinicians have unique opportunities and a growing sense of responsibility to prevent and address mental health and substance abuse problems in the medical home. In this report, the American Academy of Pediatrics proposes competencies requisite for providing mental health and substance abuse services in pediatric primary care settings and recommends steps toward achieving them. Achievement of the competencies proposed in this statement is a goal, not a current expectation. It will require innovations in residency training and continuing medical education, as well as a commitment by the individual clinician to pursue, over time, educational strategies suited to his or her learning style and skill level. System enhancements, such as collaborative relationships with mental health specialists and changes in the financing of mental health care, must precede enhancements in clinical practice. For this reason, the proposed competencies begin with knowledge and skills for systems-based practice. The proposed competencies overlap those of mental health specialists in some areas; for example, they include the knowledge and skills to care for children with attention-deficit/hyperactivity disorder, anxiety, depression, and substance abuse and to recognize psychiatric and social emergencies. In other areas, the competencies reflect the uniqueness of the primary care clinician's role: building resilience in all children; promoting healthy lifestyles; preventing or mitigating mental health and substance abuse problems; identifying risk factors and emerging mental health problems in children and their families; and partnering with families, schools, agencies, and mental health specialists to plan assessment and care. Proposed interpersonal and communication skills reflect the primary care clinician's critical role in overcoming barriers (perceived and/or experienced by children and families) to seeking help for mental health and substance abuse concerns. (6/09, reaffirmed 8/13)

GASTROESOPHAGEAL REFLUX: MANAGEMENT GUIDANCE FOR THE PEDIATRICIAN (CLINICAL REPORT)

Jenifer R. Lightdale, MD, MPH; David A. Gremse, MD; and

Section on Gastroenterology, Hepatology, and Nutrition

ABSTRACT. Recent comprehensive guidelines developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition define the common entities of gastroesophageal reflux (GER) as the physiologic passage of gastric contents into the esophagus and gastroesophageal reflux disease (GERD) as reflux associated with troublesome symptoms or complications. The ability to distinguish between GER and GERD is increasingly important to implement best practices in the management of acid reflux in patients across all pediatric age groups, as children with GERD may benefit from further evaluation and treatment, whereas conservative recommendations are the only indicated therapy in those with uncomplicated physiologic reflux. This clinical report endorses the rigorously developed, well-referenced North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines and likewise emphasizes important concepts for the general pediatrician. A key issue is distinguishing between clinical manifestations of GER and GERD in term infants, children, and adolescents to identify patients who can be managed with conservative treatment by the pediatrician and to refer patients who require consultation with the gastroenterologist. Accordingly, the evidence basis presented by the guidelines for diagnostic approaches as well as treatments is discussed. Lifestyle changes are emphasized as first-line therapy in both GER and GERD, whereas medications are explicitly indicated only for patients with GERD. Surgical therapies are reserved for children with intractable symptoms or who are at risk for life-threatening complications of GERD. Recent black box warnings from the US Food and Drug Administration are discussed, and caution is underlined when using promoters of gastric emptying and motility. Finally, attention is paid to increasing evidence of inappropriate prescriptions for proton pump inhibitors in the pediatric population. (4/13)

GENERIC PRESCRIBING, GENERIC SUBSTITUTION, AND THERAPEUTIC SUBSTITUTION

Committee on Drugs (5/87, reaffirmed 6/93, 5/96, 6/99, 5/01, 5/05, 10/08, 10/12)

GLOBAL CLIMATE CHANGE AND CHILDREN'S HEALTH *Committee on Environmental Health*

ABSTRACT. There is broad scientific consensus that Earth's climate is warming rapidly and at an accelerating rate. Human activities, primarily the burning of fossil fuels, are very likely (>90% probability) to be the main cause of this warming. Climate-sensitive changes in ecosystems are already being observed, and fundamental, potentially irreversible, ecological changes may occur in the coming decades. Conservative environmental estimates of the impact of climate changes that are already in process indicate that they will result in numerous health effects to children. The nature and extent of these changes will be greatly affected by actions taken or not taken now at the global level.

Physicians have written on the projected effects of climate change on public health, but little has been written specifically on anticipated effects of climate change on children's health. Children represent a particularly vulnerable group that is likely to suffer disproportionately from both direct and indirect adverse health effects of climate change. Pediatric health care professionals should understand these threats, anticipate their effects on children's health, and participate as children's advocates for strong mitigation and adaptation strategies now. Any solutions that address climate change must be developed within the context of overall sustainability (the use of resources by the current generation to meet current needs while ensuring that future generations will be able to meet their needs). Pediatric health care professionals can be leaders in a move away from a traditional focus on disease prevention to a broad, integrated focus on sustainability as synonymous with health.

This policy statement is supported by a technical report that examines in some depth the nature of the problem of climate change, likely effects on children's health as a result of climate change, and the critical importance of responding promptly and aggressively to reduce activities that are contributing to this change. (11/07, reaffirmed 5/12)

GLOBAL CLIMATE CHANGE AND CHILDREN'S HEALTH (TECHNICAL REPORT)

Katherine M. Shea, MD, MPH, and Committee on

Environmental Health

ABSTRACT. There is a broad scientific consensus that the global climate is warming, the process is accelerating, and that human activities are very likely (>90% probability) the main cause. This warming will have effects on ecosystems and human health, many of them adverse. Children will experience both the direct and indirect effects of climate change. Actions taken by individuals, communities, businesses, and governments will affect the magnitude and rate of global climate change and resultant health impacts. This technical report reviews the nature of the global problem and anticipated health effects on children and supports the recommendations in the accompanying policy statement on climate change and children's health. (11/07, reaffirmed 5/12)

GRADUATE MEDICAL EDUCATION AND PEDIATRIC WORKFORCE ISSUES AND PRINCIPLES

Task Force on Graduate Medical Education Reform (6/94)

GUIDANCE FOR EFFECTIVE DISCIPLINE

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. When advising families about discipline strategies, pediatricians should use a comprehensive approach that includes consideration of the parent-child relationship, reinforcement of desired behaviors, and consequences for negative behaviors. Corporal punishment is of limited effectiveness and has potentially deleterious side effects. The American Academy of Pediatrics recommends that parents be encouraged and assisted in the development of methods other than spanking for managing undesired behavior. (4/98, reaffirmed 3/01, 1/05, 5/12, 4/14)

GUIDANCE FOR THE ADMINISTRATION OF MEDICATION IN SCHOOL

Council on School Health

ABSTRACT. Many children who take medications require them during the school day. This policy statement is designed to guide prescribing health care professionals, school physicians, and school health councils on the administration of medications to children at school. All districts and schools need to have policies and plans in place for safe, effective, and efficient administration of medications at school. Having full-time licensed registered nurses administering all routine and emergency medications in schools is the best situation. When a licensed registered nurse is not available, a licensed practical nurse may administer medications. When a nurse cannot administer medication in school, the American Academy of Pediatrics supports appropriate delegation of nursing services in the school setting. Delegation is a tool that may be used by the licensed registered school nurse to allow unlicensed assistive personnel to provide standardized, routine health services under the supervision of the nurse and on the basis of physician guidance and school nursing assessment of the unique needs of the individual child and the suitability of delegation of specific nursing tasks. Any delegation of nursing duties must be consistent with the requirements of state nurse practice acts, state regulations, and guidelines provided by professional nursing organizations. Long-term, emergency, and short-term medications; over-the-counter medications; alternative medications; and experimental drugs that are administered as part of a clinical trial are discussed in this statement. This statement has been endorsed by the American School Health Association. (9/09, reaffirmed 2/13)

GUIDANCE ON MANAGEMENT OF ASYMPTOMATIC NEONATES BORN TO WOMEN WITH ACTIVE GENITAL HERPES LESIONS (CLINICAL REPORT)

Committee on Infectious Diseases and Committee on Fetus and Newborn

ABSTRACT. Herpes simplex virus (HSV) infection of the neonate is uncommon, but genital herpes infections in adults are very common. Thus, although treating an infant with neonatal herpes is a relatively rare occurrence, managing infants potentially exposed to HSV at the time of delivery occurs more frequently. The risk of transmitting HSV to an infant during delivery is determined in part by the mother's previous immunity to HSV. Women with primary genital HSV infections who are shedding HSV at delivery are 10 to 30 times more likely to transmit the virus to their newborn infants than are women with recurrent HSV infection who are shedding virus at delivery. With the availability of commercial serological tests that reliably can distinguish type-specific HSV antibodies, it is now possible to determine the type of maternal infection and, thus, further refine management of infants delivered to women who have active genital HSV lesions. The management algorithm presented herein uses both serological and virological studies to determine the risk of HSV transmission to the neonate who is delivered to a mother with active herpetic genital lesions and tailors management accordingly. The algorithm does not address the

approach to asymptomatic neonates delivered to women with a history of genital herpes but no active lesions at delivery. (1/13)

GUIDELINES FOR CARE OF CHILDREN IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. Children who require emergency care have unique needs, especially when emergencies are serious or life-threatening. The majority of ill and injured children are brought to community hospital emergency departments (EDs) by virtue of their geography within communities. Similarly, emergency medical services (EMS) agencies provide the bulk of out-of-hospital emergency care to children. It is imperative, therefore, that all hospital EDs have the appropriate resources (medications, equipment, policies, and education) and staff to provide effective emergency care for children. This statement outlines resources necessary to ensure that hospital EDs stand ready to care for children of all ages, from neonates to adolescents. These guidelines are consistent with the recommendations of the Institute of Medicine's report on the future of emergency care in the United States health system. Although resources within emergency and trauma care systems vary locally, regionally, and nationally, it is essential that hospital ED staff and administrators and EMS systems' administrators and medical directors seek to meet or exceed these guidelines in efforts to optimize the emergency care of children they serve. This statement has been endorsed by the Academic Pediatric Association, American Academy of Family Physicians, American Academy of Physician Assistants, American College of Osteopathic Emergency Physicians, American College of Surgeons, American Heart Association, American Medical Association, American Pediatric Surgical Association, Brain Injury Association of America, Child Health Corporation of America, Children's National Medical Center, Family Voices, National Association of Children's Hospitals and Related Institutions, National Association of EMS Physicians, National Association of Emergency Medical Technicians, National Association of State EMS Officials, National Committee for Quality Assurance, National PTA, Safe Kids USA, Society of Trauma Nurses, Society for Academic Emergency Medicine, and The Joint Commission. (9/09, reaffirmed 4/13)

GUIDELINES FOR DEVELOPING ADMISSION AND DISCHARGE POLICIES FOR THE PEDIATRIC INTENSIVE CARE UNIT (CLINICAL REPORT)

Committee on Hospital Care and Section on Critical Care (joint with Society of Critical Care Medicine Pediatric Section Admission Criteria Task Force)

ABSTRACT. These guidelines were developed to provide a reference for preparing policies on admission to and discharge from pediatric intensive care units. They represent a consensus opinion of physicians, nurses, and allied health care professionals. By using this document as a framework for developing multidisciplinary admission and discharge policies, use of pediatric intensive care

units can be optimized and patients can receive the level of care appropriate for their condition. (4/99, reaffirmed 5/05, 2/08, 1/13)

GUIDELINES FOR HOME CARE OF INFANTS, CHILDREN, AND ADOLESCENTS WITH CHRONIC DISEASE

Committee on Children With Disabilities (7/95, reaffirmed 4/00, 1/06)

GUIDELINES FOR MONITORING AND MANAGEMENT OF PEDIATRIC PATIENTS DURING AND AFTER SEDATION FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES: AN UPDATE (CLINICAL REPORT)

Charles J. Coté, MD; Stephen Wilson, DMD, MA, PhD; and Work Group on Sedation (joint with American Academy of Pediatric Dentistry)

ABSTRACT. The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical supervision; careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications; appropriate fasting for elective procedures and a balance between depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure; a focused airway examination for large tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction; a clear understanding of the pharmacokinetic and pharmacodynamic effects of the medications used for sedation, as well as an appreciation for drug interactions; appropriate training and skills in airway management to allow rescue of the patient; age- and size-appropriate equipment for airway management and venous access; appropriate medications and reversal agents; sufficient numbers of people to carry out the procedure and monitor the patient; appropriate physiologic monitoring during and after the procedure; a properly equipped and staffed recovery area; recovery to presedation level of consciousness before discharge from medical supervision; and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children. (12/06, reaffirmed 3/11)

GUIDELINES FOR PEDIATRIC CANCER CENTERS

Section on Hematology/Oncology

ABSTRACT. Since the American Academy of Pediatrics published guidelines for pediatric cancer centers in 1986 and 1997, significant changes in the delivery of health care have prompted a review of the role of tertiary medical centers in the care of pediatric patients. The potential effect of these changes on the treatment and survival rates of children with cancer led to this revision. The intent of this statement is to delineate personnel and facilities that are essential to provide state-of-the-art care for children and adolescents with cancer. This statement emphasizes the importance of board-certified pediatric hematologists/oncologists, pediatric subspecialty consultants, and appropriately qualified pediatric medical subspecialists and pediatric surgical specialists overseeing the care of all pediatric and adolescent cancer patients and the need

for facilities available only at a tertiary center as essential for the initial management and much of the follow-up for pediatric and adolescent cancer patients. (6/04, reaffirmed 10/08)

GUIDELINES FOR PEDIATRIC CARDIOVASCULAR CENTERS

Section on Cardiology and Cardiac Surgery

ABSTRACT. Pediatric cardiovascular centers should aim to provide high-quality therapeutic outcomes for infants and children with congenital and acquired heart diseases. This policy statement describes critical elements and organizational features of centers in which high-quality outcomes have the greatest likelihood of occurring. Center elements include noninvasive diagnostic modalities, cardiac catheterization, cardiovascular surgery, and cardiovascular intensive care. These elements should be organizationally united in centers in which pediatric cardiac physician specialists and specialized pediatric staff work together to achieve and surpass existing quality-of-care benchmarks. (3/02, reaffirmed 10/07)

GUIDELINES FOR THE DETERMINATION OF BRAIN DEATH IN INFANTS AND CHILDREN: AN UPDATE OF THE 1987 TASK FORCE RECOMMENDATIONS (CLINICAL REPORT)

Thomas A. Nakagawa, MD; Stephen Ashwal, MD;

Mudit Mathur, MD; Mohan Mysore, MD; Section on Critical Care; and Section on Neurology (joint with Society of Critical Care Medicine and Child Neurology Society)

ABSTRACT. Objective. To review and revise the 1987 pediatric brain death guidelines.

Methods. Relevant literature was reviewed. Recommendations were developed using the GRADE system.

Conclusions and Recommendations.

(1) Determination of brain death in term newborns, infants and children is a clinical diagnosis based on the absence of neurologic function with a known irreversible cause of coma. Because of insufficient data in the literature, recommendations for preterm infants less than 37 weeks gestational age are not included in this guideline.

(2) Hypotension, hypothermia, and metabolic disturbances should be treated and corrected and medications that can interfere with the neurologic examination and apnea testing should be discontinued allowing for adequate clearance before proceeding with these evaluations.

(3) Two examinations including apnea testing with each examination separated by an observation period are required. Examinations should be performed by different attending physicians. Apnea testing may be performed by the same physician. An observation period of 24 hours for term newborns (37 weeks gestational age) to 30 days of age, and 12 hours for infants and children (> 30 days to 18 years) is recommended. The first examination determines the child has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition. Assessment of neurologic function following cardiopulmonary resuscitation or other severe acute brain injuries should be deferred for 24 hours or longer if there are concerns or inconsistencies in the examination.

(4) Apnea testing to support the diagnosis of brain death must be performed safely and requires documentation of an arterial PaCO₂ 20 mm Hg above the baseline and 60 mm Hg with no respiratory effort during the testing period. If the apnea test cannot be safely completed, an ancillary study should be performed.

(5) Ancillary studies (electroencephalogram and radio-nuclide cerebral blood flow) are not required to establish brain death and are not a substitute for the neurologic examination. Ancillary studies may be used to assist the clinician in making the diagnosis of brain death (i) when components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; (iii) if a medication effect may be present; or (iv) to reduce the inter-examination observation period. When ancillary studies are used, a second clinical examination and apnea test should be performed and components that can be completed must remain consistent with brain death. In this instance the observation interval may be shortened and the second neurologic examination and apnea test (or all components that are able to be completed safely) can be performed at any time thereafter.

(6) Death is declared when the above criteria are fulfilled. (8/11)

GUIDELINES FOR THE ETHICAL CONDUCT OF STUDIES TO EVALUATE DRUGS IN PEDIATRIC POPULATIONS (CLINICAL REPORT)

Robert E. Shaddy, MD; Scott C. Denne, MD; Committee on Drugs; and Committee on Pediatric Research

ABSTRACT. The proper ethical conduct of studies to evaluate drugs in children is of paramount importance to all those involved in these types of studies. This report is an updated revision to the previously published guidelines from the American Academy of Pediatrics in 1995. Since the previous publication, there have been great strides made in the science and ethics of studying drugs in children. There have also been numerous legislative and regulatory advancements that have promoted the study of drugs in children while simultaneously allowing for the protection of this particularly vulnerable group. This report summarizes these changes and advances and provides a framework from which to guide and monitor the ethical conduct of studies to evaluate drugs in children. (3/10, reaffirmed 1/14)

GUIDELINES ON FORGOING LIFE-SUSTAINING MEDICAL TREATMENT

Committee on Bioethics (3/94, reaffirmed 11/97, 10/00, 1/04, 1/09, 10/12)

GUIDING PRINCIPLES FOR MANAGED CARE ARRANGEMENTS FOR THE HEALTH CARE OF NEWBORNS, INFANTS, CHILDREN, ADOLESCENTS, AND YOUNG ADULTS

Committee on Child Health Financing

ABSTRACT. By including the precepts of primary care and the medical home in the delivery of services, managed care can be effective in increasing access to a full range of health care services and clinicians. A carefully

designed and administered managed care plan can minimize patient under- and overutilization of services, as well as enhance quality of care. Therefore, the American Academy of Pediatrics urges the use of the key principles outlined in this statement in designing and implementing managed care programs for newborns, infants, children, adolescents, and young adults to maximize the positive potential of managed care for pediatrics. (10/13)

GUIDING PRINCIPLES FOR PEDIATRIC HOSPITAL MEDICINE PROGRAMS

Section on Hospital Medicine

ABSTRACT. Pediatric hospital medicine programs have an established place in pediatric medicine. This statement speaks to the expanded roles and responsibilities of pediatric hospitalists and their integrated role among the community of pediatricians who care for children within and outside of the hospital setting. (9/13)

GYNECOLOGIC EXAMINATION FOR ADOLESCENTS IN THE PEDIATRIC OFFICE SETTING (CLINICAL REPORT)

Paula K. Braverman, MD; Lesley Breech, MD; and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics promotes the inclusion of the gynecologic examination in the primary care setting within the medical home. Gynecologic issues are commonly seen by clinicians who provide primary care to adolescents. Some of the most common concerns include questions related to pubertal development; menstrual disorders such as dysmenorrhea, amenorrhea, oligomenorrhea, and abnormal uterine bleeding; contraception; and sexually transmitted and non-sexually transmitted infections. The gynecologic examination is a key element in assessing pubertal status and documenting physical findings. Most adolescents do not need an internal examination involving a speculum or bimanual examination. However, for cases in which more extensive examination is needed, the primary care office with the primary care clinician who has established rapport and trust with the patient is often the best setting for pelvic examination. This report reviews the gynecologic examination, including indications for the pelvic examination in adolescents and the approach to this examination in the office setting. Indications for referral to a gynecologist are included. The pelvic examination may be successfully completed when conducted without pressure and approached as a normal part of routine young women's health care. (8/10, reaffirmed 5/13)

HEAD LICE (CLINICAL REPORT)

Barbara L. Frankowski, MD, MPH; Joseph A. Bocchini, Jr, MD; Council on School Health; and Committee on Infectious Diseases

ABSTRACT. Head lice infestation is associated with limited morbidity but causes a high level of anxiety among parents of school-aged children. Since the 2002 clinical report on head lice was published by the American Academy of Pediatrics, patterns of resistance to products available over-the-counter and by prescription have changed, and additional mechanical means of removing head lice have been explored. This revised clinical report clarifies current diagnosis and treatment protocols and

provides guidance for the management of children with head lice in the school setting. (7/10)

HEALTH AND MENTAL HEALTH NEEDS OF CHILDREN IN US MILITARY FAMILIES (CLINICAL REPORT)

Benjamin S. Siegel, MD; Beth Ellen Davis, MD, MPH;

Committee on Psychosocial Aspects of Child and Family Health; and Section on Uniformed Services

ABSTRACT. The wars in Afghanistan and Iraq have been challenging for US uniformed service families and their children. Almost 60% of US service members have family responsibilities. Approximately 2.3 million active duty, National Guard, and Reserve service members have been deployed since the beginning of the wars in Afghanistan and Iraq (2001 and 2003, respectively), and almost half have deployed more than once, some for up to 18 months' duration. Up to 2 million US children have been exposed to a wartime deployment of a loved one in the past 10 years. Many service members have returned from combat deployments with symptoms of posttraumatic stress disorder, depression, anxiety, substance abuse, and traumatic brain injury. The mental health and well-being of spouses, significant others, children (and their friends), and extended family members of deployed service members continues to be significantly challenged by the experiences of wartime deployment as well as by combat mortality and morbidity. The medical system of the Department of Defense provides health and mental health services for active duty service members and their families as well as activated National Guard and Reserve service members and their families. In addition to military pediatricians and civilian pediatricians employed by military treatment facilities, nonmilitary general pediatricians care for >50% of children and family members before, during, and after wartime deployments. This clinical report is for all pediatricians, both active duty and civilian, to aid in caring for children whose loved ones have been, are, or will be deployed. (5/13)

HEALTH CARE FOR YOUTH IN THE JUVENILE JUSTICE SYSTEM

Committee on Adolescence

ABSTRACT. Youth in the juvenile correctional system are a high-risk population who, in many cases, have unmet physical, developmental, and mental health needs. Multiple studies have found that some of these health issues occur at higher rates than in the general adolescent population. Although some youth in the juvenile justice system have interfaced with health care providers in their community on a regular basis, others have had inconsistent or nonexistent care. The health needs of these youth are commonly identified when they are admitted to a juvenile custodial facility. Pediatricians and other health care providers play an important role in the care of these youth, and continuity between the community and the correctional facility is crucial. This policy statement provides an overview of the health needs of youth in the juvenile correctional system, including existing resources and standards for care, financing of health care within correctional facilities, and evidence-based interventions. Recommendations are provided for the provision of health

care services to youth in the juvenile correctional system as well as specific areas for advocacy efforts. (11/11)

HEALTH CARE OF YOUTH AGING OUT OF FOSTER CARE

Council on Foster Care, Adoption, and Kinship Care and Committee on Early Childhood

ABSTRACT. Youth transitioning out of foster care face significant medical and mental health care needs. Unfortunately, these youth rarely receive the services they need because of lack of health insurance. Through many policies and programs, the federal government has taken steps to support older youth in foster care and those aging out. The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub L No. 110-354) requires states to work with youth to develop a transition plan that addresses issues such as health insurance. In addition, beginning in 2014, the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111-148) makes youth aging out of foster care eligible for Medicaid coverage until age 26 years, regardless of income. Pediatricians can support youth aging out of foster care by working collaboratively with the child welfare agency in their state to ensure that the ongoing health needs of transitioning youth are met. (11/12)

HEALTH CARE SUPERVISION FOR CHILDREN WITH WILLIAMS SYNDROME

Committee on Genetics

ABSTRACT. This set of guidelines is designed to assist the pediatrician to care for children with Williams syndrome diagnosed by clinical features and with regional chromosomal microdeletion confirmed by fluorescence in situ hybridization. (5/01, reaffirmed 5/05, 1/09)

HEALTH EQUITY AND CHILDREN'S RIGHTS

Council on Community Pediatrics and Committee on Native American Child Health

ABSTRACT. Many children in the United States fail to reach their full health and developmental potential. Disparities in their health and well-being result from the complex interplay of multiple social and environmental determinants that are not adequately addressed by current standards of pediatric practice or public policy. Integrating the principles and practice of child health equity—children's rights, social justice, human capital investment, and health equity ethics—into pediatrics will address the root causes of child health disparities.

Promoting the principles and practice of equity-based clinical care, child advocacy, and child- and family-centered public policy will help to ensure that social and environmental determinants contribute positively to the health and well-being of children. The American Academy of Pediatrics and pediatricians can move the national focus from documenting child health disparities to advancing the principles and practice of child health equity and, in so doing, influence the worldwide practice of pediatrics and child health. All pediatricians, including primary care practitioners and medical and surgical subspecialists, can incorporate these principles into their practice of pediatrics and child health. Integration of these

principles into competency-based training and board certification will secure their assimilation into all levels of pediatric practice. (3/10, reaffirmed 10/13)

HEALTH INFORMATION TECHNOLOGY AND THE MEDICAL HOME

Council on Clinical Information Technology

ABSTRACT. The American Academy of Pediatrics (AAP) supports development and universal implementation of a comprehensive electronic infrastructure to support pediatric information functions of the medical home. These functions include (1) timely and continuous management and tracking of health data and services over a patient's lifetime for all providers, patients, families, and guardians, (2) comprehensive organization and secure transfer of health data during patient-care transitions between providers, institutions, and practices, (3) establishment and maintenance of central coordination of a patient's health information among multiple repositories (including personal health records and information exchanges), (4) translation of evidence into actionable clinical decision support, and (5) reuse of archived clinical data for continuous quality improvement. The AAP supports universal, secure, and vendor-neutral portability of health information for all patients contained within the medical home across all care settings (ambulatory practices, inpatient settings, emergency departments, pharmacies, consultants, support service providers, and therapists) for multiple purposes including direct care, personal health records, public health, and registries. The AAP also supports financial incentives that promote the development of information tools that meet the needs of pediatric workflows and that appropriately recognize the added value of medical homes to pediatric care. (4/11)

HEALTH SUPERVISION FOR CHILDREN WITH ACHONDROPLASIA (CLINICAL REPORT)

Tracy L. Trotter, MD; Judith G. Hall, OC, MD; and Committee on Genetics

ABSTRACT. Achondroplasia is the most common condition associated with disproportionate short stature. Substantial information is available concerning the natural history and anticipatory health supervision needs in children with this dwarfing disorder. Most children with achondroplasia have delayed motor milestones, problems with persistent or recurrent middle-ear dysfunction, and bowing of the lower legs. Less often, infants and children may have serious health consequences related to hydrocephalus, craniocervical junction compression, upper-airway obstruction, or thoracolumbar kyphosis. Anticipatory care should be directed at identifying children who are at high risk and intervening to prevent serious sequelae. This report is designed to help the pediatrician care for children with achondroplasia and their families. (9/05, reaffirmed 5/12)

HEALTH SUPERVISION FOR CHILDREN WITH DOWN SYNDROME (CLINICAL REPORT)



Marilyn J. Bull, MD, and Committee on Genetics

ABSTRACT. These guidelines are designed to assist the pediatrician in caring for the child in whom a diagnosis of Down syndrome has been confirmed by chromosome analysis. Although a pediatrician's initial contact with the child is usually during infancy, occasionally the pregnant woman who has been given a prenatal diagnosis of Down syndrome will be referred for review of the condition and the genetic counseling provided. Therefore, this report offers guidance for this situation as well. (7/11)

HEALTH SUPERVISION FOR CHILDREN WITH FRAGILE X SYNDROME (CLINICAL REPORT)

Joseph H. Hersh, MD; Robert A. Saul, MD; and Committee on Genetics

ABSTRACT. Fragile X syndrome (an FMR1-related disorder) is the most commonly inherited form of mental retardation. Early physical recognition is difficult, so boys with developmental delay should be strongly considered for molecular testing. The characteristic adult phenotype usually does not develop until the second decade of life. Girls can also be affected with developmental delay. Because multiple family members can be affected with mental retardation and other conditions (premature ovarian failure and tremor/ataxia), family history information is of critical importance for the diagnosis and management of affected patients and their families. This report summarizes issues for fragile X syndrome regarding clinical diagnosis, laboratory diagnosis, genetic counseling, related health problems, behavior management, and age-related health supervision guidelines. The diagnosis of fragile X syndrome not only involves the affected children but also potentially has significant health consequences for multiple generations in each family. (4/11)

HEALTH SUPERVISION FOR CHILDREN WITH MARFAN SYNDROME (CLINICAL REPORT)

Brad T. Tinkle, MD, PhD; Howard M. Saal, MD; and Committee on Genetics

ABSTRACT. Marfan syndrome is a systemic, heritable connective tissue disorder that affects many different organ systems and is best managed by using a multidisciplinary approach. The guidance in this report is designed to assist the pediatrician in recognizing the features of Marfan syndrome as well as caring for the individual with this disorder. (9/13)

HEALTH SUPERVISION FOR CHILDREN WITH NEUROFIBROMATOSIS (CLINICAL REPORT)

Joseph H. Hersh, MD, and Committee on Genetics

ABSTRACT. Neurofibromatosis 1 is a multisystem disorder that primarily involves the skin and nervous system. Its population prevalence is 1 in 3500. The condition usually is recognized in early childhood, when cutaneous manifestations are apparent. Although neurofibromatosis 1 is associated with marked clinical variability, most affected children do well from the standpoint of their growth and development. Some features of neurofibromatosis 1 are present at birth, and others are age-related

abnormalities of tissue proliferation, which necessitate periodic monitoring to address ongoing health and developmental needs and to minimize the risk of serious medical complications. This clinical report provides a review of the clinical criteria needed to establish a diagnosis, the inheritance pattern of neurofibromatosis 1, its major clinical and developmental manifestations, and guidelines for monitoring and providing intervention to maximize the growth, development, and health of an affected child. (3/08)

HEALTH SUPERVISION FOR CHILDREN WITH PRADER-WILLI SYNDROME (CLINICAL REPORT)

Shawn E. McCandless, MD, and Committee on Genetics

ABSTRACT. This set of guidelines was designed to assist the pediatrician in caring for children with Prader-Willi syndrome diagnosed by clinical features and confirmed by molecular testing. Prader-Willi syndrome provides an excellent example of how early diagnosis and management can improve the long-term outcome for some genetic disorders. (12/10)

HEALTH SUPERVISION FOR CHILDREN WITH SICKLE CELL DISEASE

Section on Hematology/Oncology and Committee on Genetics

ABSTRACT. Sickle cell disease (SCD) is a group of complex genetic disorders with multisystem manifestations. This statement provides pediatricians in primary care and subspecialty practice with an overview of the genetics, diagnosis, clinical manifestations, and treatment of SCD. Specialized comprehensive medical care decreases morbidity and mortality during childhood. The provision of comprehensive care is a time-intensive endeavor that includes ongoing patient and family education, periodic comprehensive evaluations and other disease-specific health maintenance services, psychosocial care, and genetic counseling. Timely and appropriate treatment of acute illness is critical, because life-threatening complications develop rapidly. It is essential that every child with SCD receive comprehensive care that is coordinated through a medical home with appropriate expertise. (3/02, reaffirmed 1/06, 1/11)

HEARING ASSESSMENT IN INFANTS AND CHILDREN: RECOMMENDATIONS

BEYOND NEONATAL SCREENING (CLINICAL REPORT)

Allen D. "Buz" Harlor Jr, MD; Charles Bower, MD;

Committee on Practice and Ambulatory Medicine; and

Section on Otolaryngology–Head and Neck Surgery

ABSTRACT. Congenital or acquired hearing loss in infants and children has been linked with lifelong deficits in speech and language acquisition, poor academic performance, personal-social maladjustments, and emotional difficulties. Identification of hearing loss through neonatal hearing screening, regular surveillance of developmental milestones, auditory skills, parental concerns, and middle-ear status and objective hearing screening of all infants and children at critical developmental stages can prevent or reduce many of these adverse consequences. This report promotes a proactive, consistent, and explicit

process for the early identification of children with hearing loss in the medical home. An algorithm of the recommended approach has been developed to assist in the detection and documentation of, and intervention for, hearing loss. (9/09)

HELPING CHILDREN AND FAMILIES DEAL WITH DIVORCE AND SEPARATION (CLINICAL REPORT)

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. More than 1 million children each year experience their parents' divorce. For these children and their parents, this process can be emotionally traumatic from the beginning of parental disagreement and rancor, through the divorce, and often for many years thereafter. Pediatricians are encouraged to be aware of behavioral changes in their patients that might be signals of family dysfunction so they can help parents and children understand and deal more positively with the issue. Age-appropriate explanation and counseling is important so children realize that they are not the cause of, and cannot be the cure for, the divorce. Pediatricians can offer families guidance in dealing with their children through the troubled time as well as appropriate lists of reading material and, if indicated, can refer them to professionals with expertise in the emotional, social, and legal aspects of divorce and its aftermath. (11/02, reaffirmed 1/06)

HIGH-DEDUCTIBLE HEALTH PLANS

Committee on Child Health Financing

ABSTRACT. High-deductible health plans (HDHPs) are insurance policies with higher deductibles than conventional plans. The Medicare Prescription Drug Improvement and Modernization Act of 2003 linked many HDHPs with tax-advantaged spending accounts. The 2010 Patient Protection and Affordable Care Act continues to provide for HDHPs in its lower-level plans on the health insurance marketplace and provides for them in employer-offered plans. HDHPs decrease the premium cost of insurance policies for purchasers and shift the risk of further payments to the individual subscriber. HDHPs reduce utilization and total medical costs, at least in the short term. Because HDHPs require out-of-pocket payment in the initial stages of care, primary care and other outpatient services as well as elective procedures are the services most affected, whereas higher-cost services in the health care system, incurred after the deductible is met, are unaffected. HDHPs promote adverse selection because healthier and wealthier patients tend to opt out of conventional plans in favor of HDHPs. Because the ill pay more than the healthy under HDHPs, families with children with special health care needs bear an increased cost burden in this model. HDHPs discourage use of nonpreventive primary care and thus are at odds with most recommendations for improving the organization of health care, which focus on strengthening primary care.

This policy statement provides background information on HDHPs, discusses the implications for families and pediatric care providers, and suggests courses of action. (4/14)

See full text on page 681.



HIGH-DEDUCTIBLE HEALTH PLANS AND THE NEW RISKS OF CONSUMER-DRIVEN HEALTH INSURANCE PRODUCTS

Committee on Child Health Financing

ABSTRACT. Consumer-driven health care is the most noteworthy development in health insurance since the widespread adoption of health maintenance organizations and preferred provider organizations in the 1980s. The most common consumer-driven health plan is the high-deductible health plan, which is essentially a catastrophic health insurance plan, often linked with tax-advantaged spending accounts, with very high deductibles, fewer benefits, and higher cost-sharing than conventional health maintenance organization or preferred provider organization plans. The financial risks are significant under high-deductible health plans, especially for low- to moderate-income families and for families whose children have special health care needs. Of concern for pediatricians are the potential quality risks that are predictable in high-deductible health plans, in which families are likely to delay or avoid seeking care, especially preventive care (if it is not exempted from the deductible), when they are faced with paying for care before the deductible is met. This policy statement provides background information on the most common consumer-driven health plan model, discusses the implications for pediatricians and families, and offers recommendations pertaining to health plan product design, education, practice administration, and research. (3/07)

HIV TESTING AND PROPHYLAXIS TO PREVENT MOTHER-TO-CHILD TRANSMISSION IN THE UNITED STATES

Committee on Pediatric AIDS

ABSTRACT. Universal HIV testing of pregnant women in the United States is the key to prevention of mother-to-child transmission of HIV. Repeat testing in the third trimester and rapid HIV testing at labor and delivery are additional strategies to further reduce the rate of perinatal HIV transmission. Prevention of mother-to-child transmission of HIV is most effective when antiretroviral drugs are received by the mother during her pregnancy and continued through delivery and then administered to the infant after birth. Antiretroviral drugs are effective in reducing the risk of mother-to-child transmission of HIV even when prophylaxis is started for the infant soon after birth. New rapid testing methods allow identification of HIV-infected women or HIV-exposed infants in 20 to 60 minutes. The American Academy of Pediatrics recommends documented, routine HIV testing for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing ("opt-out" consent or "right of refusal"). For women in labor with undocumented HIV-infection status during the current pregnancy, immediate maternal HIV testing with opt-out consent, using a rapid HIV antibody test, is recommended. Positive HIV antibody screening test results should be confirmed with immunofluorescent antibody or Western blot assay. For women with a positive rapid HIV antibody test result, antiretroviral prophylaxis should be administered promptly to the mother and newborn infant

on the basis of the positive result of the rapid antibody test without waiting for results of confirmatory HIV testing. If the confirmatory test result is negative, then prophylaxis should be discontinued. For a newborn infant whose mother's HIV serostatus is unknown, the health care professional should perform rapid HIV antibody testing on the mother or on the newborn infant, with results reported to the health care professional no later than 12 hours after the infant's birth. If the rapid HIV antibody test result is positive, antiretroviral prophylaxis should be instituted as soon as possible after birth but certainly by 12 hours after delivery, pending completion of confirmatory HIV testing. The mother should be counseled not to breastfeed the infant. Assistance with immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test result may be negative. If the confirmatory test result is negative, then prophylaxis should be stopped and breastfeeding may be initiated. If the confirmatory test result is positive, infants should receive antiretroviral prophylaxis for 6 weeks after birth, and the mother should not breastfeed the infant. (11/08, reaffirmed 6/11)

HOME, HOSPITAL, AND OTHER NON-SCHOOL-BASED INSTRUCTION FOR CHILDREN AND ADOLESCENTS WHO ARE MEDICALLY UNABLE TO ATTEND SCHOOL

Committee on School Health

ABSTRACT. The American Academy of Pediatrics recommends that school-aged children and adolescents obtain their education in school in the least restrictive setting, that is, the setting most conducive to learning for the particular student. However, at times, acute illness or injury and chronic medical conditions preclude school attendance. This statement is meant to assist evaluation and planning for children to receive non-school-based instruction and to return to school at the earliest possible date. (11/00, reaffirmed 6/03, 5/06)

HOME CARE OF CHILDREN AND YOUTH WITH COMPLEX HEALTH CARE NEEDS AND TECHNOLOGY DEPENDENCIES (CLINICAL REPORT)

Ellen Roy Elias, MD; Nancy A. Murphy, MD; and Council on Children With Disabilities

ABSTRACT. Children and youth with complex medical issues, especially those with technology dependencies, experience frequent and often lengthy hospitalizations. Hospital discharges for these children can be a complicated process that requires a deliberate, multistep approach. In addition to successful discharges to home, it is essential that pediatric providers develop and implement an interdisciplinary and coordinated plan of care that addresses the child's ongoing health care needs. The goal is to ensure that each child remains healthy, thrives, and obtains optimal medical home and developmental supports that promote ongoing care at home and minimize recurrent hospitalizations. This clinical report presents an approach to discharging the child with complex medical needs with technology dependencies from hospital to home and then continually addressing the needs of the child and family in the home environment. (4/12)

HONORING DO-NOT-ATTEMPT-RESUSCITATION REQUESTS IN SCHOOLS

Council on School Health and Committee on Bioethics

ABSTRACT. Increasingly, children and adolescents with complex chronic conditions are living in the community. Federal legislation and regulations facilitate their participation in school. Some of these children and adolescents and their families may wish to forego life-sustaining medical treatment, including cardiopulmonary resuscitation, because they would be ineffective or because the risks outweigh the benefits. Honoring these requests in the school environment is complex because of the limited availability of school nurses and the frequent lack of supporting state legislation and regulations. Understanding and collaboration on the part of all parties is essential. Pediatricians have an important role in helping school nurses incorporate a specific action plan into the student's individualized health care plan. The action plan should include both communication and comfort-care plans. Pediatricians who work directly with schools can also help implement policies, and professional organizations can advocate for regulations and legislation that enable students and their families to effectuate their preferences. (4/10, reaffirmed 7/13)

HOSPITAL DISCHARGE OF THE HIGH-RISK NEONATE

Committee on Fetus and Newborn

ABSTRACT. This policy statement updates the guidelines on discharge of the high-risk neonate first published by the American Academy of Pediatrics in 1998. As with the earlier document, this statement is based, insofar as possible, on published, scientifically derived information. This updated statement incorporates new knowledge about risks and medical care of the high-risk neonate, the timing of discharge, and planning for care after discharge. It also refers to other American Academy of Pediatrics publications that are relevant to these issues. This statement draws on the previous classification of high-risk infants into 4 categories: (1) the preterm infant; (2) the infant with special health care needs or dependence on technology; (3) the infant at risk because of family issues; and (4) the infant with anticipated early death. The issues of deciding when discharge is appropriate, defining the specific needs for follow-up care, and the process of detailed discharge planning are addressed as they apply in general to all 4 categories; in addition, special attention is directed to the particular issues presented by the 4 individual categories. Recommendations are given to aid in deciding when discharge is appropriate and to ensure that all necessary care will be available and well coordinated after discharge. The need for individualized planning and physician judgment is emphasized. (11/08, reaffirmed 5/11)

THE HOSPITAL RECORD OF THE INJURED CHILD AND THE NEED FOR EXTERNAL CAUSE-OF-INJURY CODES

Committee on Injury and Poison Prevention

ABSTRACT. Proper record-keeping of emergency department visits and hospitalizations of injured children is vital for appropriate patient management. Determination and documentation of the circumstances surrounding the injury event are essential. This information not only is the

basis for preventive counseling, but also provides clues about how similar injuries in other youth can be avoided. The hospital records have an important secondary purpose; namely, if sufficient information about the cause and mechanism of injury is documented, it can be subsequently coded, electronically compiled, and retrieved later to provide an epidemiologic profile of the injury, the first step in prevention at the population level. To be of greatest use, hospital records should indicate the "who, what, when, where, why, and how" of the injury occurrence and whether protective equipment (eg, a seat belt) was used. The pediatrician has two important roles in this area: to document fully the injury event and to advocate the use of standardized external cause-of-injury codes, which allow such data to be compiled and analyzed. (2/99, reaffirmed 5/02, 5/05, 10/08, 10/13)

HOSPITAL STAY FOR HEALTHY TERM NEWBORNS

Committee on Fetus and Newborn

ABSTRACT. The hospital stay of the mother and her healthy term newborn infant should be long enough to allow identification of early problems and to ensure that the family is able and prepared to care for the infant at home. The length of stay should also accommodate the unique characteristics of each mother-infant dyad, including the health of the mother, the health and stability of the infant, the ability and confidence of the mother to care for her infant, the adequacy of support systems at home, and access to appropriate follow-up care. Input from the mother and her obstetrician should be considered before a decision to discharge a newborn is made, and all efforts should be made to keep mothers and infants together to promote simultaneous discharge. (1/10)

HPV VACCINE RECOMMENDATIONS

Committee on Infectious Diseases

ABSTRACT. On October 25, 2011, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention recommended that the quadrivalent human papillomavirus vaccine (Gardasil; Merck & Co, Inc, Whitehouse Station, NJ) be used routinely in males. The American Academy of Pediatrics has reviewed updated data provided by the Advisory Committee on Immunization Practices on vaccine efficacy, safety, and cost-effectiveness as well as programmatic considerations and supports this recommendation. This revised statement updates recommendations for human papillomavirus immunization of both males and females. (2/12)

HUMAN EMBRYONIC STEM CELL (hESC) AND HUMAN EMBRYO RESEARCH

Committee on Pediatric Research and Committee on Bioethics

ABSTRACT. Human embryonic stem cell research has emerged as an important platform for the understanding and treatment of pediatric diseases. From its inception, however, it has raised ethical concerns based not on the use of stem cells themselves but on objections to the source of the cells—specifically, the destruction of preimplantation human embryos. Despite differences in public opinion on this issue, a large majority of the public supports continued research using embryonic stem cells.

Given the possible substantial benefit of stem cell research on child health and development, the American Academy of Pediatrics believes that funding and oversight for human embryo and embryonic stem cell research should continue. (10/12)

HUMAN IMMUNODEFICIENCY VIRUS AND OTHER BLOOD-BORNE VIRAL PATHOGENS IN THE ATHLETIC SETTING

Committee on Sports Medicine and Fitness

ABSTRACT. Because athletes and the staff of athletic programs can be exposed to blood during athletic activity, they have a very small risk of becoming infected with human immunodeficiency virus, hepatitis B virus, or hepatitis C virus. This statement, which updates a previous position statement of the American Academy of Pediatrics, discusses sports participation for athletes infected with these pathogens and the precautions needed to reduce the risk of infection to others in the athletic setting. Each of the recommendations in this statement is dependent upon and intended to be considered with reference to the other recommendations in this statement and not in isolation. (12/99, reaffirmed 1/05, 1/09, 11/11)

HUMAN IMMUNODEFICIENCY VIRUS SCREENING

Committee on Fetus and Newborn and Committee on Pediatric AIDS (joint with American College of Obstetricians and Gynecologists) (7/99, reaffirmed 6/02, 5/05, 10/08, 5/12)

HUMAN MILK, BREASTFEEDING, AND TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS IN THE UNITED STATES

Committee on Pediatric AIDS (11/95, reaffirmed 11/99, 11/03, 2/08)

HUMAN MILK, BREASTFEEDING, AND TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 IN THE UNITED STATES (TECHNICAL REPORT)

Committee on Pediatric AIDS

ABSTRACT. Transmission of human immunodeficiency virus type 1 (HIV-1) through breastfeeding has been conclusively demonstrated. The risk of such transmission has been quantified, the timing has been clarified, and certain risk factors for breastfeeding transmission have been identified. In areas where infant formula is accessible, affordable, safe, and sustainable, avoidance of breastfeeding has represented one of the main components of mother-to-child HIV-1 transmission prevention efforts for many years. In areas where affordable and safe alternatives to breastfeeding may not be available, interventions to prevent breastfeeding transmission are being investigated. Complete avoidance of breastfeeding by HIV-1-infected women has been recommended by the American Academy of Pediatrics and the Centers for Disease Control and Prevention and remains the only means by which prevention of breastfeeding transmission of HIV-1 can be absolutely ensured. This technical report summarizes the information available regarding breastfeeding transmission of HIV-1. (11/03, reaffirmed 1/07)

HYPOTHERMIA AND NEONATAL ENCEPHALOPATHY (CLINICAL REPORT)

Committee on Fetus and Newborn

ABSTRACT. Data from large randomized clinical trials indicate that therapeutic hypothermia, using either selective head cooling or systemic cooling, is an effective therapy for neonatal encephalopathy. Infants selected for cooling must meet the criteria outlined in published clinical trials. The implementation of cooling needs to be performed at centers that have the capability to manage medically complex infants. Because the majority of infants who have neonatal encephalopathy are born at community hospitals, centers that perform cooling should work with their referring hospitals to implement education programs focused on increasing the awareness and identification of infants at risk for encephalopathy, and the initial clinical management of affected infants. (5/14)

See full text on page 693.

IDENTIFICATION AND CARE OF HIV-EXPOSED AND HIV-INFECTED INFANTS, CHILDREN, AND ADOLESCENTS IN FOSTER CARE

Committee on Pediatric AIDS

ABSTRACT. As a consequence of the expanding human immunodeficiency virus (HIV) epidemic and major advances in medical management of HIV-exposed and HIV-infected persons, revised recommendations are provided for HIV testing of infants, children, and adolescents in foster care. Updated recommendations also are provided for the care of HIV-exposed and HIV-infected persons who are in foster care. (7/00, reaffirmed 3/03, 2/08, 6/11)

IDENTIFICATION AND EVALUATION OF CHILDREN WITH AUTISM SPECTRUM DISORDERS (CLINICAL REPORT)

Chris Plauché Johnson, MD, MEd; Scott M. Myers, MD; and Council on Children With Disabilities

ABSTRACT. Autism spectrum disorders are not rare; many primary care pediatricians care for several children with autism spectrum disorders. Pediatricians play an important role in early recognition of autism spectrum disorders, because they usually are the first point of contact for parents. Parents are now much more aware of the early signs of autism spectrum disorders because of frequent coverage in the media; if their child demonstrates any of the published signs, they will most likely raise their concerns to their child's pediatrician. It is important that pediatricians be able to recognize the signs and symptoms of autism spectrum disorders and have a strategy for assessing them systematically. Pediatricians also must be aware of local resources that can assist in making a definitive diagnosis of, and in managing, autism spectrum disorders. The pediatrician must be familiar with developmental, educational, and community resources as well as medical subspecialty clinics. This clinical report is 1 of 2 documents that replace the original American Academy of Pediatrics policy statement and technical report published in 2001. This report addresses background information, including definition, history, epidemiology, diagnostic criteria, early signs, neuropathologic aspects, and etiologic possibilities in autism spectrum



disorders. In addition, this report provides an algorithm to help the pediatrician develop a strategy for early identification of children with autism spectrum disorders. The accompanying clinical report addresses the management of children with autism spectrum disorders and follows this report on page 1162 [available at www.pediatrics.org/cgi/content/full/120/5/1162]. Both clinical reports are complemented by the toolkit titled "*Autism: Caring for Children With Autism Spectrum Disorders: A Resource Toolkit for Clinicians*," which contains screening and surveillance tools, practical forms, tables, and parent handouts to assist the pediatrician in the identification, evaluation, and management of autism spectrum disorders in children. (11/07, reaffirmed 9/10, 8/14)

IDENTIFICATION AND MANAGEMENT OF EATING DISORDERS IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

David S. Rosen, MD, MPH, and Committee on Adolescence

ABSTRACT. The incidence and prevalence of eating disorders in children and adolescents has increased significantly in recent decades, making it essential for pediatricians to consider these disorders in appropriate clinical settings, to evaluate patients suspected of having these disorders, and to manage (or refer) patients in whom eating disorders are diagnosed. This clinical report includes a discussion of diagnostic criteria and outlines the initial evaluation of the patient with disordered eating. Medical complications of eating disorders may affect any organ system, and careful monitoring for these complications is required. The range of treatment options, including pharmacotherapy, is described in this report. Pediatricians are encouraged to advocate for legislation and policies that ensure appropriate services for patients with eating disorders, including medical care, nutritional intervention, mental health treatment, and care coordination. (11/10)

IDENTIFYING INFANTS AND YOUNG CHILDREN WITH DEVELOPMENTAL DISORDERS IN THE MEDICAL HOME: AN ALGORITHM FOR DEVELOPMENTAL SURVEILLANCE AND SCREENING



Council on Children With Disabilities, Section on Developmental and Behavioral Pediatrics, Bright Futures Steering Committee, and Medical Home Initiatives for Children With Special Needs Project Advisory Committee

ABSTRACT. Early identification of developmental disorders is critical to the well-being of children and their families. It is an integral function of the primary care medical home and an appropriate responsibility of all pediatric health care professionals. This statement provides an algorithm as a strategy to support health care professionals in developing a pattern and practice for addressing developmental concerns in children from birth through 3 years of age. The authors recommend that developmental surveillance be incorporated at every well-child preventive care visit. Any concerns raised during surveillance should be promptly addressed with standardized developmental screening tests. In addition, screening tests should be administered regularly at the 9-, 18-, and 30-month visits. (Because the 30-month visit is not yet a part of the preventive care system and is often not reimbursable by third-

party payers at this time, developmental screening can be performed at 24 months of age. In addition, because the frequency of regular pediatric visits decreases after 24 months of age, a pediatrician who expects that his or her patients will have difficulty attending a 30-month visit should conduct screening during the 24-month visit.) The early identification of developmental problems should lead to further developmental and medical evaluation, diagnosis, and treatment, including early developmental intervention. Children diagnosed with developmental disorders should be identified as children with special health care needs, and chronic-condition management should be initiated. Identification of a developmental disorder and its underlying etiology may also drive a range of treatment planning, from medical treatment of the child to family planning for his or her parents. (7/06, reaffirmed 12/09, 8/14)

IMMERSION IN WATER DURING LABOR AND DELIVERY (CLINICAL REPORT)

Committee on Fetus and Newborn (joint with American College of Obstetricians and Gynecologists Committee on Obstetric Practice)

ABSTRACT. Immersion in water has been suggested as a beneficial alternative for labor, delivery, or both and over the past decades has gained popularity in many parts of the world. Immersion in water during the first stage of labor may be associated with decreased pain or use of anesthesia and decreased duration of labor. However, there is no evidence that immersion in water during the first stage of labor otherwise improves perinatal outcomes, and it should not prevent or inhibit other elements of care. The safety and efficacy of immersion in water during the second stage of labor have not been established, and immersion in water during the second stage of labor has not been associated with maternal or fetal benefit. Given these facts and case reports of rare but serious adverse effects in the newborn, the practice of immersion in the second stage of labor (underwater delivery) should be considered an experimental procedure that only should be performed within the context of an appropriately designed clinical trial with informed consent. Facilities that plan to offer immersion in the first stage of labor need to establish rigorous protocols for candidate selection, maintenance and cleaning of tubs and immersion pools, infection control procedures, monitoring of mothers and fetuses at appropriate intervals while immersed, and immediately and safely moving women out of the tubs if maternal or fetal concerns develop. (3/14)

See full text on page 701.

IMMUNIZATION FOR STREPTOCOCCUS PNEUMONIAE INFECTIONS IN HIGH-RISK CHILDREN

Committee on Infectious Diseases

ABSTRACT. Routine use of the pneumococcal conjugate vaccines (PCV7 and PCV13), beginning in 2000, has resulted in a dramatic reduction in the incidence of invasive pneumococcal disease (IPD) attributable to serotypes of *Streptococcus pneumoniae* contained in the vaccines. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommend the

expanded use of PCV13 in children 6 through 18 years of age with certain conditions that place them at elevated risk of IPD. This statement provides recommendations for the use of PCV13 in children 6 through 18 years. A single dose of PCV13 should be administered to certain children in this age group who are at elevated risk of IPD. Recommendations for the use of PCV13 in healthy children and for pneumococcal polysaccharide vaccine (PPSV23) remain unchanged. (11/14)

See full text on page 707.

IMMUNIZATION INFORMATION SYSTEMS

Committee on Practice and Ambulatory Medicine

ABSTRACT. The American Academy of Pediatrics continues to support the development and implementation of immunization information systems, previously referred to as immunization registries, and other systems for the benefit of children, pediatricians, and their communities. Pediatricians and others must be aware of the value that immunization information systems have for society, the potential fiscal influences on their practice, the costs and benefits, and areas for future improvement. (9/06, reaffirmed 10/11)

IMMUNIZING PARENTS AND OTHER CLOSE FAMILY CONTACTS IN THE PEDIATRIC OFFICE SETTING (TECHNICAL REPORT)

Herschel R. Lessin, MD; Kathryn M. Edwards, MD;

Committee on Practice and Ambulatory Medicine; and

Committee on Infectious Diseases

ABSTRACT. Additional strategies are needed to protect children from vaccine-preventable diseases. In particular, very young infants, as well as children who are immunocompromised, are at especially high risk for developing the serious consequences of vaccine-preventable diseases and cannot be immunized completely. There is some evidence that children who become infected with these diseases are exposed to pathogens through household contacts, particularly from parents or other close family contacts. Such infections likely are attributable to adults who are not fully protected from these diseases, either because their immunity to vaccine-preventable diseases has waned over time or because they have not received a vaccine. There are many challenges that have added to low adult immunization rates in the United States. One option to increase immunization coverage for parents and close family contacts of infants and vulnerable children is to provide alternative locations for these adults to be immunized, such as the pediatric office setting. Ideally, adults should receive immunizations in their medical homes; however, to provide greater protection to these adults and reduce the exposure of children to pathogens, immunizing parents or other adult family contacts in the pediatric office setting could increase immunization coverage for this population to protect themselves as well as children to whom they provide care. (12/11)

IMPACT OF MUSIC, MUSIC LYRICS, AND MUSIC VIDEOS ON CHILDREN AND YOUTH

Council on Communications and Media

ABSTRACT. Music plays an important role in the socialization of children and adolescents. Popular music is pres-

ent almost everywhere, and it is easily available through the radio, various recordings, the Internet, and new technologies, allowing adolescents to hear it in diverse settings and situations, alone or shared with friends. Parents often are unaware of the lyrics to which their children are listening because of the increasing use of downloaded music and headphones. Research on popular music has explored its effects on schoolwork, social interactions, mood and affect, and particularly behavior. The effect that popular music has on children's and adolescents' behavior and emotions is of paramount concern. Lyrics have become more explicit in their references to drugs, sex, and violence over the years, particularly in certain genres. A teenager's preference for certain types of music could be correlated or associated with certain behaviors. As with popular music, the perception and the effect of music-video messages are important, because research has reported that exposure to violence, sexual messages, sexual stereotypes, and use of substances of abuse in music videos might produce significant changes in behaviors and attitudes of young viewers. Pediatricians and parents should be aware of this information. Furthermore, with the evidence portrayed in these studies, it is essential for pediatricians and parents to take a stand regarding music lyrics. (10/09)

THE IMPACT OF SOCIAL MEDIA ON CHILDREN, ADOLESCENTS, AND FAMILIES (CLINICAL REPORT)

Geonn Schurgin O'Keeffe, MD; Kathleen Clarke-Pearson,

MD; and Council on Communications and Media

ABSTRACT. Using social media Web sites is among the most common activity of today's children and adolescents. Any Web site that allows social interaction is considered a social media site, including social networking sites such as Facebook, MySpace, and Twitter; gaming sites and virtual worlds such as Club Penguin, Second Life, and the Sims; video sites such as YouTube; and blogs. Such sites offer today's youth a portal for entertainment and communication and have grown exponentially in recent years. For this reason, it is important that parents become aware of the nature of social media sites, given that not all of them are healthy environments for children and adolescents. Pediatricians are in a unique position to help families understand these sites and to encourage healthy use and urge parents to monitor for potential problems with cyberbullying, "Facebook depression," sexting, and exposure to inappropriate content. (3/11)

THE IMPORTANCE OF PLAY IN PROMOTING HEALTHY CHILD DEVELOPMENT AND MAINTAINING STRONG PARENT-CHILD BONDS (CLINICAL REPORT)

Kenneth R. Ginsburg, MD, MEd; Committee on

Communications; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Play is essential to development because it contributes to the cognitive, physical, social, and emotional well-being of children and youth. Play also offers an ideal opportunity for parents to engage fully with their children. Despite the benefits derived from play for both children and parents, time for free play has been markedly reduced for some children. This report addresses a variety of factors that have reduced play, including a hurried lifestyle, changes in family structure, and increased atten-

tion to academics and enrichment activities at the expense of recess or free child-centered play. This report offers guidelines on how pediatricians can advocate for children by helping families, school systems, and communities consider how best to ensure that play is protected as they seek the balance in children's lives to create the optimal developmental milieu. (1/07)

THE IMPORTANCE OF PLAY IN PROMOTING HEALTHY CHILD DEVELOPMENT AND MAINTAINING STRONG PARENT-CHILD BOND: FOCUS ON CHILDREN IN POVERTY (CLINICAL REPORT)

*Regina M. Milteer, MD; Kenneth R. Ginsburg, MD, MEd;
Council on Communications and Media; and Committee on
Psychosocial Aspects of Child and Family Health*

ABSTRACT. Play is essential to the social, emotional, cognitive, and physical well-being of children beginning in early childhood. It is a natural tool for children to develop resiliency as they learn to cooperate, overcome challenges, and negotiate with others. Play also allows children to be creative. It provides time for parents to be fully engaged with their children, to bond with their children, and to see the world from the perspective of their child. However, children who live in poverty often face socioeconomic obstacles that impede their rights to have playtime, thus affecting their healthy social-emotional development. For children who are underresourced to reach their highest potential, it is essential that parents, educators, and pediatricians recognize the importance of lifelong benefits that children gain from play. (12/11)

IMPROVING SUBSTANCE ABUSE PREVENTION, ASSESSMENT, AND TREATMENT FINANCING FOR CHILDREN AND ADOLESCENTS

*Committee on Child Health Financing and Committee on
Substance Abuse*

ABSTRACT. The numbers of children, adolescents, and families affected by substance abuse have sharply increased since the early 1990s. The American Academy of Pediatrics recognizes the scope and urgency of this problem and has developed this policy statement for consideration by Congress, federal and state agencies, employers, national organizations, health care professionals, health insurers, managed care organizations, advocacy groups, and families. (10/01)

THE INAPPROPRIATE USE OF SCHOOL "READINESS" TESTS

*Committee on Early Childhood, Adoption, and Dependent
Care and Committee on School Health (3/95, reaffirmed
4/98, 1/04, 4/10)*

INCORPORATING RECOGNITION AND MANAGEMENT OF PERINATAL AND POSTPARTUM DEPRESSION INTO PEDIATRIC PRACTICE (CLINICAL REPORT)

*Marian F. Earls, MD, and Committee on Psychosocial Aspects
of Child and Family Health*

ABSTRACT. Every year, more than 400 000 infants are born to mothers who are depressed, which makes perinatal depression the most underdiagnosed obstetric complication in America. Postpartum depression leads to increased costs of medical care, inappropriate medical care, child abuse and neglect, discontinuation of breast-

feeding, and family dysfunction and adversely affects early brain development. Pediatric practices, as medical homes, can establish a system to implement postpartum depression screening and to identify and use community resources for the treatment and referral of the depressed mother and support for the mother-child (dyad) relationship. This system would have a positive effect on the health and well-being of the infant and family. State chapters of the American Academy of Pediatrics, working with state Early Periodic Screening, Diagnosis, and Treatment (EPSDT) and maternal and child health programs, can increase awareness of the need for perinatal depression screening in the obstetric and pediatric periodicity of care schedules and ensure payment. Pediatricians must advocate for workforce development for professionals who care for very young children and for promotion of evidence-based interventions focused on healthy attachment and parent-child relationships. (10/10)

INCREASING ANTIRETROVIRAL DRUG ACCESS FOR CHILDREN WITH HIV INFECTION

*Committee on Pediatric AIDS and Section on International
Child Health*

ABSTRACT. Although there have been great gains in the prevention of pediatric HIV infection and provision of antiretroviral therapy for children with HIV infection in resource-rich countries, many barriers remain to scaling up HIV prevention and treatment for children in resource-limited areas of the world. Appropriate testing technologies need to be made more widely available to identify HIV infection in infants. Training of practitioners in the skills required to care for children with HIV infection is required to increase the number of children receiving antiretroviral therapy. Lack of availability of appropriate antiretroviral drug formulations that are easily usable and inexpensive is a major impediment to optimal care for children with HIV. The time and energy spent trying to develop liquid antiretroviral formulations might be better used in the manufacture of smaller pill sizes or crushable tablets, which are easier to dispense, transport, store, and administer to children. (4/07, reaffirmed 4/10)

INCREASING IMMUNIZATION COVERAGE

*Committee on Practice and Ambulatory Medicine and Council
on Community Pediatrics*

ABSTRACT. In 1977, the American Academy of Pediatrics issued a statement calling for universal immunization of all children for whom vaccines are not contraindicated. In 1995, the policy statement "Implementation of the Immunization Policy" was published by the American Academy of Pediatrics, followed in 2003 with publication of the first version of this statement, "Increasing Immunization Coverage." Since 2003, there have continued to be improvements in immunization coverage, with progress toward meeting the goals set forth in *Healthy People 2010*. Data from the 2007 National Immunization Survey showed that 90% of children 19 to 35 months of age have received recommended doses of each of the following vaccines: inactivated poliovirus (IPV), measles-mumps-rubella (MMR), varicella-zoster virus (VZB), hepatitis B virus (HBV), and *Haemophilus influenzae* type b (Hib). For diphtheria and tetanus and acellular pertussis

(DTaP) vaccine, 84.5% have received the recommended 4 doses by 35 months of age. Nevertheless, the *Healthy People 2010* goal of at least 80% coverage for the full series (at least 4 doses of DTaP, 3 doses of IPV, 1 dose of MMR, 3 doses of Hib, 3 doses of HBV, and 1 dose of varicella-zoster virus vaccine) has not yet been met, and immunization coverage of adolescents continues to lag behind the goals set forth in *Healthy People 2010*. Despite these encouraging data, a vast number of new challenges that threaten continued success toward the goal of universal immunization coverage have emerged. These challenges include an increase in new vaccines and new vaccine combinations as well as a significant number of vaccines currently under development; a dramatic increase in the acquisition cost of vaccines, coupled with a lack of adequate payment to practitioners to buy and administer vaccines; unanticipated manufacturing and delivery problems that have caused significant shortages of various vaccine products; and the rise of a public antivaccination movement that uses the Internet as well as standard media outlets to advance a position, wholly unsupported by any scientific evidence, linking vaccines with various childhood conditions, particularly autism. Much remains to be accomplished by physician organizations; vaccine manufacturers; third-party payers; the media; and local, state, and federal governments to ensure dependable vaccine supply and payments that are sufficient to continue to provide immunizations in public and private settings and to promote effective strategies to combat unjustified misstatements by the antivaccination movement.

Pediatricians should work individually and collectively at the local, state, and national levels to ensure that all children without a valid contraindication receive all childhood immunizations on time. Pediatricians and pediatric organizations, in conjunction with government agencies such as the Centers for Disease Control and Prevention, must communicate effectively with parents to maximize their understanding of the overall safety and efficacy of vaccines. Most parents and children have not experienced many of the vaccine-preventable diseases, and the general public is not well informed about the risks and sequelae of these conditions. A number of recommendations are included for pediatricians, individually and collectively, to support further progress toward the goal of universal immunization coverage of all children for whom vaccines are not contraindicated. (5/10)

INDICATIONS FOR MANAGEMENT AND REFERRAL OF PATIENTS INVOLVED IN SUBSTANCE ABUSE

Committee on Substance Abuse

ABSTRACT. This statement addresses the challenge of evaluating and managing the various stages of substance use by children and adolescents in the context of pediatric practice. Approaches are suggested that would assist the pediatrician in differentiating highly prevalent experimental and occasional use from more severe use with adverse consequences that affect emotional, behavioral, educational, or physical health. Comorbid psychiatric conditions are common and should be evaluated and treated simultaneously by child and adolescent mental health specialists. Guidelines for referral based on severity of involvement using established patient treatment-match-

ing criteria are outlined. Pediatricians need to become familiar with treatment professionals and facilities in their communities and to ensure that treatment for adolescent patients is appropriate based on their developmental, psychosocial, medical, and mental health needs. The family should be encouraged to participate actively in the treatment process. (7/00)

INFANT FEEDING AND TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS IN THE UNITED STATES

Committee on Pediatric AIDS

ABSTRACT. Physicians caring for infants born to women infected with HIV are likely to be involved in providing guidance to HIV-infected mothers on appropriate infant feeding practices. It is critical that physicians are aware of the HIV transmission risk from human milk and the current recommendations for feeding HIV-exposed infants in the United States. Because the only intervention to completely prevent HIV transmission via human milk is not to breastfeed, in the United States, where clean water and affordable replacement feeding are available, the American Academy of Pediatrics recommends that HIV-infected mothers not breastfeed their infants, regardless of maternal viral load and antiretroviral therapy. (1/13)

INFANT METHEMOGLOBINEMIA: THE ROLE OF DIETARY NITRATE IN FOOD AND WATER (CLINICAL REPORT)

Frank R. Greer, MD; Michael Shannon, MD; Committee on Nutrition; and Committee on Environmental Health

ABSTRACT. Infants for whom formula may be prepared with well water remain a high-risk group for nitrate poisoning. This clinical report reinforces the need for testing of well water for nitrate content. There seems to be little or no risk of nitrate poisoning from commercially prepared infant foods in the United States. However, reports of nitrate poisoning from home-prepared vegetable foods for infants continue to occur. Breastfeeding infants are not at risk of methemoglobinemia even when mothers ingest water with very high concentrations of nitrate nitrogen (100 ppm). (9/05, reaffirmed 4/09)

INFECTION PREVENTION AND CONTROL IN PEDIATRIC AMBULATORY SETTINGS

Committee on Infectious Diseases

ABSTRACT. Since the American Academy of Pediatrics published a statement titled "Infection Control in Physicians' Offices" (*Pediatrics*. 2000;105[6]:1361-1369), there have been significant changes that prompted this updated statement. Infection prevention and control is an integral part of pediatric practice in ambulatory medical settings as well as in hospitals. Infection prevention and control practices should begin at the time the ambulatory visit is scheduled. All health care personnel should be educated regarding the routes of transmission and techniques used to prevent transmission of infectious agents. Policies for infection prevention and control should be written, readily available, updated annually, and enforced. The standard precautions for hospitalized patients from the Centers for Disease Control and Prevention, with a modification from the American Academy of Pediatrics exempting the use of gloves for routine diaper changes and wiping a well child's nose or tears, are appropriate

for most patient encounters. As employers, pediatricians are required by the Occupational Safety and Health Administration to take precautions to identify and protect employees who are likely to be exposed to blood or other potentially infectious materials while on the job. Key principles of standard precautions include hand hygiene (ie, use of alcohol-based hand rub or hand-washing with soap [plain or antimicrobial] and water) before and after every patient contact; implementation of respiratory hygiene and cough-etiquette strategies for patients with suspected influenza or infection with another respiratory tract pathogen to the extent feasible; separation of infected, contagious children from uninfected children when feasible; safe handling and disposal of needles and other sharp medical devices and evaluation and implementation of needle-safety devices; appropriate use of personal protective equipment such as gloves, gowns, masks, and eye protection; and appropriate sterilization, disinfection, and antisepsis. (9/07, reaffirmed 8/10)

INFORMED CONSENT, PARENTAL PERMISSION, AND ASSENT IN PEDIATRIC PRACTICE

Committee on Bioethics (2/95, reaffirmed 11/98, 11/02, 10/06, 5/11)

INHALANT ABUSE (CLINICAL REPORT)

Janet F. Williams, MD; Michael Storck, MD; Committee on Substance Abuse; and Committee on Native American Child Health

ABSTRACT. Inhalant abuse is the intentional inhalation of a volatile substance for the purpose of achieving an altered mental state. As an important, yet-underrecognized form of substance abuse, inhalant abuse crosses all demographic, ethnic, and socioeconomic boundaries, causing significant morbidity and mortality in school-aged and older children. This clinical report reviews key aspects of inhalant abuse, emphasizes the need for greater awareness, and offers advice regarding the pediatrician's role in the prevention and management of this substance abuse problem. (5/07)

INJURIES ASSOCIATED WITH INFANT WALKERS

Committee on Injury and Poison Prevention

ABSTRACT. In 1999, an estimated 8800 children younger than 15 months were treated in hospital emergency departments in the United States for injuries associated with infant walkers. Thirty-four infant walker-related deaths were reported from 1973 through 1998. The vast majority of injuries occur from falls down stairs, and head injuries are common. Walkers do not help a child learn to walk; indeed, they can delay normal motor and mental development. The use of warning labels, public education, adult supervision during walker use, and stair gates have all been demonstrated to be insufficient strategies to prevent injuries associated with infant walkers. To comply with the revised voluntary standard (ASTM F977-96), walkers manufactured after June 30, 1997, must be wider than a 36-in doorway or must have a braking mechanism designed to stop the walker if 1 or more wheels drop off the riding surface, such as at the top of a stairway.

Because data indicate a considerable risk of major and minor injury and even death from the use of infant walkers, and because there is no clear benefit from their use, the American Academy of Pediatrics recommends a ban on the manufacture and sale of mobile infant walkers. If a parent insists on using a mobile infant walker, it is vital that they choose a walker that meets the performance standards of ASTM F977-96 to prevent falls down stairs. Stationary activity centers should be promoted as a safer alternative to mobile infant walkers. (9/01, reaffirmed 1/05, 2/08, 10/11)

INJURIES IN YOUTH SOCCER (CLINICAL REPORT)

Chris G. Koutures, MD; Andrew J. M. Gregory, MD; and Council on Sports Medicine and Fitness

ABSTRACT. Injury rates in youth soccer, known as football outside the United States, are higher than in many other contact/collision sports and have greater relative numbers in younger, preadolescent players. With regard to musculoskeletal injuries, young females tend to suffer more knee injuries, and young males suffer more ankle injuries. Concussions are fairly prevalent in soccer as a result of contact/collision rather than purposeful attempts at heading the ball. Appropriate rule enforcement and emphasis on safe play can reduce the risk of soccer-related injuries. This report serves as a basis for encouraging safe participation in soccer for children and adolescents. (1/10, reaffirmed 5/13)

INJURY RISK OF NONPOWDER GUNS (TECHNICAL REPORT)

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Nonpowder guns (ball-bearing [BB] guns, pellet guns, air rifles, paintball guns) continue to cause serious injuries to children and adolescents. The muzzle velocity of these guns can range from approximately 150 ft/second to 1200 ft/second (the muzzle velocities of traditional firearm pistols are 750 ft/second to 1450 ft/second). Both low- and high-velocity nonpowder guns are associated with serious injuries, and fatalities can result from high-velocity guns. A persisting problem is the lack of medical recognition of the severity of injuries that can result from these guns, including penetration of the eye, skin, internal organs, and bone. Nationally, in 2000, there were an estimated 21840 (coefficient of variation: 0.0821) injuries related to nonpowder guns, with approximately 4% resulting in hospitalization. Between 1990 and 2000, the US Consumer Product Safety Commission reported 39 nonpowder gun-related deaths, of which 32 were children younger than 15 years. The introduction of high-powered air rifles in the 1970s has been associated with approximately 4 deaths per year. The advent of war games and the use of paintball guns have resulted in a number of reports of injuries, especially to the eye. Injuries associated with nonpowder guns should receive prompt medical management similar to the management of firearm-related injuries, and nonpowder guns should never be characterized as toys. (11/04, reaffirmed 2/08, 10/11)

IN-LINE SKATING INJURIES IN CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention and Committee on Sports Medicine and Fitness

ABSTRACT. In-line skating has become one of the fastest-growing recreational sports in the United States. Recent studies emphasize the value of protective gear in reducing the incidence of injuries. Recommendations are provided for parents and pediatricians, with special emphasis on the novice or inexperienced skater. (4/98, reaffirmed 1/02, 1/06, 1/09, 11/11)

INSTITUTIONAL ETHICS COMMITTEES

Committee on Bioethics

ABSTRACT. In hospitals throughout the United States, institutional ethics committees (IECs) have become a standard vehicle for the education of health professionals about biomedical ethics, for the drafting and review of hospital policy, and for clinical ethics case consultation. In addition, there is increasing interest in a role for the IEC in organizational ethics. Recommendations are made about the membership and structure of an IEC, and guidelines are provided for those serving on an ethics committee. (1/01, reaffirmed 1/04, 1/09, 10/12, 7/14)

INSTRUMENT-BASED PEDIATRIC VISION SCREENING POLICY STATEMENT

Section on Ophthalmology and Committee on Practice and Ambulatory Medicine (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. A policy statement describing the use of automated vision screening technology (instrument-based vision screening) is presented. Screening for amblyogenic refractive error with instrument-based screening is not dependent on behavioral responses of children, as when visual acuity is measured. Instrument-based screening is quick, requires minimal cooperation of the child, and is especially useful in the preverbal, preliterate, or developmentally delayed child. Children younger than 4 years can benefit from instrument-based screening, and visual acuity testing can be used reliably in older children. Adoption of this new technology is highly dependent on third-party payment policies, which could present a significant barrier to adoption. (10/12)

INSUFFICIENT SLEEP IN ADOLESCENTS AND YOUNG ADULTS: AN UPDATE ON CAUSES AND CONSEQUENCES (TECHNICAL REPORT)

Judith Owens, MD, MPH, FAAP; Adolescent Sleep Working Group; and Committee on Adolescence

ABSTRACT. Chronic sleep loss and associated sleepiness and daytime impairments in adolescence are a serious threat to the academic success, health, and safety of our nation's youth and an important public health issue. Understanding the extent and potential short- and long-term repercussions of sleep restriction, as well as the unhealthy sleep practices and environmental factors that contribute to sleep loss in adolescents, is key in setting public policies to mitigate these effects and in counseling patients and families in the clinical setting. This report reviews the current literature on sleep patterns in ado-

lescents, factors contributing to chronic sleep loss (ie, electronic media use, caffeine consumption), and health-related consequences, such as depression, increased obesity risk, and higher rates of drowsy driving accidents. The report also discusses the potential role of later school start times as a means of reducing adolescent sleepiness. (8/14)

See full text on page 713.

INSURANCE COVERAGE OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES FOR CHILDREN AND ADOLESCENTS: A CONSENSUS STATEMENT

American Academy of Pediatrics and Others (10/00)

INTENSIVE TRAINING AND SPORTS SPECIALIZATION IN YOUNG ATHLETES

Committee on Sports Medicine and Fitness

ABSTRACT. Children involved in sports should be encouraged to participate in a variety of different activities and develop a wide range of skills. Young athletes who specialize in just one sport may be denied the benefits of varied activity while facing additional physical, physiologic, and psychologic demands from intense training and competition.

This statement reviews the potential risks of high-intensity training and sports specialization in young athletes. Pediatricians who recognize these risks can have a key role in monitoring the health of these young athletes and helping reduce risks associated with high-level sports participation. (7/00, reaffirmed 11/04, 1/06, 5/09)

INTERFERON- γ RELEASE ASSAYS FOR DIAGNOSIS OF TUBERCULOSIS INFECTION AND DISEASE IN CHILDREN (TECHNICAL REPORT)

Jeffrey R. Starke, MD, FAAP, and Committee on Infectious Diseases

ABSTRACT. Tuberculosis (TB) remains an important problem among children in the United States and throughout the world. Although diagnosis and treatment of infection with *Mycobacterium tuberculosis* (also referred to as latent tuberculosis infection [LTBI] or TB infection) remain the lynchpins of TB prevention, there is no diagnostic reference standard for LTBI. The tuberculin skin test (TST) has many limitations, including difficulty in administration and interpretation, the need for a return visit by the patient, and false-positive results caused by significant cross-reaction with *Mycobacterium bovis*-bacille Calmette-Guérin (BCG) vaccines and many nontuberculous mycobacteria. Interferon- γ release assays (IGRAs) are blood tests that measure ex vivo T-lymphocyte release of interferon- γ after stimulation by antigens specific for *M tuberculosis*. Because these antigens are not found on *M bovis*-BCG or most nontuberculous mycobacteria, IGRAs are more specific tests than the TST, yielding fewer false-positive results. However, IGRAs have little advantage over the TST in sensitivity, and both methods have reduced sensitivity in immunocompromised children, including children with severe TB disease. Both methods have a higher positive predictive value when applied to children with risk factors for LTBI. Unfortunately, neither method distinguishes between TB infection and TB disease. The objective of this technical report is to review what IGRAs are most useful for: (1) increasing test speci-

ficity in children who have received a BCG vaccine and may have a false-positive TST result; (2) using with the TST to increase sensitivity for finding LTBI in patients at high risk of developing progression from LTBI to disease; and (3) helping to diagnose TB disease. (11/14)

See full text on page 727.

INTIMATE PARTNER VIOLENCE: THE ROLE OF THE PEDIATRICIAN (CLINICAL REPORT)

Jonathan D. Thackeray, MD; Roberta Hibbard, MD; M. Denise Dowd, MD, MPH; Committee on Child Abuse and Neglect; and Committee on Injury, Violence, and Poison Prevention

ABSTRACT. The American Academy of Pediatrics and its members recognize the importance of improving the physician's ability to recognize intimate partner violence (IPV) and understand its effects on child health and development and its role in the continuum of family violence. Pediatricians are in a unique position to identify abused caregivers in pediatric settings and to evaluate and treat children raised in homes in which IPV may occur. Children exposed to IPV are at increased risk of being abused and neglected and are more likely to develop adverse health, behavioral, psychological, and social disorders later in life. Identifying IPV, therefore, may be one of the most effective means of preventing child abuse and identifying caregivers and children who may be in need of treatment and/or therapy. Pediatricians should be aware of the profound effects of exposure to IPV on children. (4/10, reaffirmed 1/14)

IODINE DEFICIENCY, POLLUTANT CHEMICALS, AND THE THYROID: NEW INFORMATION ON AN OLD PROBLEM

Council on Environmental Health

ABSTRACT. Many women of reproductive age in the United States are marginally iodine deficient, perhaps because the salt in processed foods is not iodized. Iodine deficiency, per se, can interfere with normal brain development in their offspring; in addition, it increases vulnerability to the effects of certain environmental pollutants, such as nitrate, thiocyanate, and perchlorate. Although pregnant and lactating women should take a supplement containing adequate iodide, only about 15% do so. Such supplements, however, may not contain enough iodide and may not be labeled accurately. The American Thyroid Association recommends that pregnant and lactating women take a supplement with adequate iodide. The American Academy of Pediatrics recommends that pregnant and lactating women also avoid exposure to excess nitrate, which would usually occur from contaminated well water, and thiocyanate, which is in cigarette smoke. Perchlorate is currently a candidate for regulation as a water pollutant. The Environmental Protection Agency should proceed with appropriate regulation, and the Food and Drug Administration should address the mislabeling of the iodine content of prenatal/lactation supplements. (5/14)

See full text on page 741.

LACTOSE INTOLERANCE IN INFANTS, CHILDREN, AND ADOLESCENTS (CLINICAL REPORT)

Melvin B. Heyman, MD, MPH, for Committee on Nutrition
ABSTRACT. The American Academy of Pediatrics Committee on Nutrition presents an updated review of lactose intolerance in infants, children, and adolescents. Differences between primary, secondary, congenital, and developmental lactase deficiency that may result in lactose intolerance are discussed. Children with suspected lactose intolerance can be assessed clinically by dietary lactose elimination or by tests including noninvasive hydrogen breath testing or invasive intestinal biopsy determination of lactase (and other disaccharidase) concentrations. Treatment consists of use of lactase-treated dairy products or oral lactase supplementation, limitation of lactose-containing foods, or dairy elimination. The American Academy of Pediatrics supports use of dairy foods as an important source of calcium for bone mineral health and of other nutrients that facilitate growth in children and adolescents. If dairy products are eliminated, other dietary sources of calcium or calcium supplements need to be provided. (9/06, reaffirmed 8/12)

"LATE-PRETERM" INFANTS: A POPULATION AT RISK (CLINICAL REPORT)

William A. Engle, MD; Kay M. Tomashek, MD; Carol Wallman, MSN; and Committee on Fetus and Newborn
ABSTRACT. Late-preterm infants, defined by birth at 34% through 36% weeks' gestation, are less physiologically and metabolically mature than term infants. Thus, they are at higher risk of morbidity and mortality than term infants. The purpose of this report is to define "late preterm," recommend a change in terminology from "near term" to "late preterm," present the characteristics of late-preterm infants that predispose them to a higher risk of morbidity and mortality than term infants, and propose guidelines for the evaluation and management of these infants after birth. (12/07, reaffirmed 5/10)

LAWN MOWER-RELATED INJURIES TO CHILDREN

Committee on Injury and Poison Prevention
ABSTRACT. Lawn mower-related injuries to children are relatively common and can result in severe injury or death. Many amputations during childhood are caused by power mowers. Pediatricians have an important role as advocates and educators to promote the prevention of these injuries. (6/01, reaffirmed 10/04, 5/07, 6/10)

LAWN MOWER-RELATED INJURIES TO CHILDREN (TECHNICAL REPORT)

Committee on Injury and Poison Prevention
ABSTRACT. In the United States, approximately 9400 children younger than 18 years receive emergency treatment annually for lawn mower-related injuries. More than 7% of these children require hospitalization, and power mowers cause a large proportion of the amputations during childhood. Prevention of lawn mower-related injuries can be achieved by design changes of lawn mowers, guidelines for mower operation, and education of parents, child caregivers, and children. Pediatricians have an important role as advocates and educators to promote the prevention of these injuries. (6/01, reaffirmed 10/04, 5/07, 6/10)

LEARNING DISABILITIES, DYSLEXIA, AND VISION

Section on Ophthalmology and Council on Children

With Disabilities (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. Learning disabilities, including reading disabilities, are commonly diagnosed in children. Their etiologies are multifactorial, reflecting genetic influences and dysfunction of brain systems. Learning disabilities are complex problems that require complex solutions. Early recognition and referral to qualified educational professionals for evidence-based evaluations and treatments seem necessary to achieve the best possible outcome. Most experts believe that dyslexia is a language-based disorder. Vision problems can interfere with the process of learning; however, vision problems are not the cause of primary dyslexia or learning disabilities. Scientific evidence does not support the efficacy of eye exercises, behavioral vision therapy, or special tinted filters or lenses for improving the long-term educational performance in these complex pediatric neurocognitive conditions. Diagnostic and treatment approaches that lack scientific evidence of efficacy, including eye exercises, behavioral vision therapy, or special tinted filters or lenses, are not endorsed and should not be recommended. (7/09, reaffirmed 7/14)

LEARNING DISABILITIES, DYSLEXIA, AND VISION (TECHNICAL REPORT)

Sheryl M. Handler, MD; Walter M. Fierson, MD; and Section on Ophthalmology and Council on Children With Disabilities (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. Learning disabilities constitute a diverse group of disorders in which children who generally possess at least average intelligence have problems processing information or generating output. Their etiologies are multifactorial and reflect genetic influences and dysfunction of brain systems. Reading disability, or dyslexia, is the most common learning disability. It is a receptive language-based learning disability that is characterized by difficulties with decoding, fluent word recognition, rapid automatic naming, and/or reading-comprehension skills. These difficulties typically result from a deficit in the phonologic component of language that makes it difficult to use the alphabetic code to decode the written word. Early recognition and referral to qualified professionals for evidence-based evaluations and treatments are necessary to achieve the best possible outcome. Because dyslexia is a language-based disorder, treatment should be directed at this etiology. Remedial programs should include specific instruction in decoding, fluency training, vocabulary, and comprehension. Most programs include daily intensive individualized instruction that explicitly teaches phonemic awareness and the application of phonics. Vision problems can interfere with the process of reading, but children with dyslexia or related learning disabilities have the same visual function and ocular health as children without such conditions. Currently, there is inadequate

scientific evidence to support the view that subtle eye or visual problems cause or increase the severity of learning disabilities. Because they are difficult for the public to understand and for educators to treat, learning disabilities have spawned a wide variety of scientifically unsupported vision-based diagnostic and treatment procedures. Scientific evidence does not support the claims that visual training, muscle exercises, ocular pursuit-and-tracking exercises, behavioral/perceptual vision therapy, "training" glasses, prisms, and colored lenses and filters are effective direct or indirect treatments for learning disabilities. There is no valid evidence that children who participate in vision therapy are more responsive to educational instruction than children who do not participate. (3/11)

LEGALIZATION OF MARIJUANA: POTENTIAL IMPACT ON YOUTH

Committee on Substance Abuse and Committee on Adolescence

ABSTRACT. As experts in the health care of children and adolescents, pediatricians may be called on to advise legislators concerning the potential impact of changes in the legal status of marijuana on adolescents. Parents, too, may look to pediatricians for advice as they consider whether to support state-level initiatives that propose to legalize the use of marijuana for medical purposes or to decriminalize possession of small amounts of marijuana. This policy statement provides the position of the American Academy of Pediatrics on the issue of marijuana legalization, and the accompanying technical report (available online) reviews what is currently known about the relationship between adolescents' use of marijuana and its legal status to better understand how change might influence the degree of marijuana use by adolescents in the future. (6/04)

LEGALIZATION OF MARIJUANA: POTENTIAL IMPACT ON YOUTH (TECHNICAL REPORT)

Committee on Substance Abuse and Committee on Adolescence

ABSTRACT. This technical report provides historical perspectives and comparisons of various approaches to the legal status of marijuana to aid in forming public policy. Information on the impact that decriminalization and legalization of marijuana could have on adolescents, in addition to concerns surrounding medicinal use of marijuana, are also addressed in this report. Recommendations are included in the accompanying policy statement. (6/04)

LEVELS OF NEONATAL CARE

Committee on Fetus and Newborn

ABSTRACT. Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. (8/12)

THE LIFELONG EFFECTS OF EARLY CHILDHOOD ADVERSITY AND TOXIC STRESS (TECHNICAL REPORT)

Jack P. Shonkoff, MD; Andrew S. Garner, MD, PhD;

Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Advances in fields of inquiry as diverse as neuroscience, molecular biology, genomics, developmental psychology, epidemiology, sociology, and economics are catalyzing an important paradigm shift in our understanding of health and disease across the lifespan. This converging, multidisciplinary science of human development has profound implications for our ability to enhance the life prospects of children and to strengthen the social and economic fabric of society. Drawing on these multiple streams of investigation, this report presents an ecobiodevelopmental framework that illustrates how early experiences and environmental influences can leave a lasting signature on the genetic predispositions that affect emerging brain architecture and long-term health. The report also examines extensive evidence of the disruptive impacts of toxic stress, offering intriguing insights into causal mechanisms that link early adversity to later impairments in learning, behavior, and both physical and mental well-being. The implications of this framework for the practice of medicine, in general, and pediatrics, specifically, are potentially transformational. They suggest that many adult diseases should be viewed as developmental disorders that begin early in life and that persistent health disparities associated with poverty, discrimination, or maltreatment could be reduced by the alleviation of toxic stress in childhood. An ecobiodevelopmental framework also underscores the need for new thinking about the focus and boundaries of pediatric practice. It calls for pediatricians to serve as both front-line guardians of healthy child development and strategically positioned, community leaders to inform new science-based strategies that build strong foundations for educational achievement, economic productivity, responsible citizenship, and lifelong health. (12/11)

LITERACY PROMOTION: AN ESSENTIAL COMPONENT OF PRIMARY CARE PEDIATRIC PRACTICE

Council on Early Childhood

ABSTRACT. Reading regularly with young children stimulates optimal patterns of brain development and strengthens parent-child relationships at a critical time in child development, which, in turn, builds language, literacy, and social-emotional skills that last a lifetime. Pediatric providers have a unique opportunity to encourage parents to engage in this important and enjoyable activity with their children beginning in infancy. Research has revealed that parents listen and children learn as a result of literacy promotion by pediatricians, which provides a practical and evidence-based opportunity to support early brain development in primary care practice. The American Academy of Pediatrics (AAP) recommends that pediatric providers promote early literacy development for children beginning in infancy and continuing at least until the age of kindergarten entry by (1) advising all parents that reading aloud with young children can enhance

parent-child relationships and prepare young minds to learn language and early literacy skills; (2) counseling all parents about developmentally appropriate shared-reading activities that are enjoyable for children and their parents and offer language-rich exposure to books, pictures, and the written word; (3) providing developmentally appropriate books given at health supervision visits for all high-risk, low-income young children; (4) using a robust spectrum of options to support and promote these efforts; and (5) partnering with other child advocates to influence national messaging and policies that support and promote these key early shared-reading experiences. The AAP supports federal and state funding for children's books to be provided at pediatric health supervision visits to children at high risk living at or near the poverty threshold and the integration of literacy promotion, an essential component of pediatric primary care, into pediatric resident education. This policy statement is supported by the AAP technical report "School Readiness" and supports the AAP policy statement "Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health." (7/14)

See full text on page 747.

LONG-TERM FOLLOW-UP CARE FOR PEDIATRIC CANCER SURVIVORS (CLINICAL REPORT)

Section on Hematology/Oncology (joint with Children's Oncology Group)

ABSTRACT. Progress in therapy has made survival into adulthood a reality for most children, adolescents, and young adults diagnosed with cancer today. Notably, this growing population remains vulnerable to a variety of long-term therapy-related sequelae. Systematic ongoing follow-up of these patients, therefore, is important for providing for early detection of and intervention for potentially serious late-onset complications. In addition, health counseling and promotion of healthy lifestyles are important aspects of long-term follow-up care to promote risk reduction for health problems that commonly present during adulthood. Both general and subspecialty pediatric health care providers are playing an increasingly important role in the ongoing care of childhood cancer survivors, beyond the routine preventive care, health supervision, and anticipatory guidance provided to all patients. This report is based on the guidelines that have been developed by the Children's Oncology Group to facilitate comprehensive long-term follow-up of childhood cancer survivors (www.survivorshipguidelines.org). (3/09, reaffirmed 4/13)

MAINTAINING AND IMPROVING THE ORAL HEALTH OF YOUNG CHILDREN

Section on Oral Health

ABSTRACT. Oral health is an integral part of the overall health of children. Dental caries is a common and chronic disease process with significant short- and long-term consequences. The prevalence of dental caries for the youngest of children has not decreased over the past decade, despite improvements for older children. As health care professionals responsible for the overall health of children, pediatricians frequently confront morbidity associated with dental caries. Because the youngest children

visit the pediatrician more often than they visit the dentist, it is important that pediatricians be knowledgeable about the disease process of dental caries, prevention of the disease, and interventions available to the pediatrician and the family to maintain and restore health. (11/14)

See full text on page 755.

MALE ADOLESCENT SEXUAL AND REPRODUCTIVE HEALTH CARE (CLINICAL REPORT)

Arik V. Marcell, MD, MPH; Charles Wibbelsman, MD;

Warren M. Seigel, MD; and Committee on Adolescence

ABSTRACT. Male adolescents' sexual and reproductive health needs often go unmet in the primary care setting. This report discusses specific issues related to male adolescents' sexual and reproductive health care in the context of primary care, including pubertal and sexual development, sexual behavior, consequences of sexual behavior, and methods of preventing sexually transmitted infections (including HIV) and pregnancy. Pediatricians are encouraged to address male adolescent sexual and reproductive health on a regular basis, including taking a sexual history, performing an appropriate examination, providing patient-centered and age-appropriate anticipatory guidance, and delivering appropriate vaccinations. Pediatricians should provide these services to male adolescent patients in a confidential and culturally appropriate manner, promote healthy sexual relationships and responsibility, and involve parents in age-appropriate discussions about sexual health with their sons. (11/11)

MALE CIRCUMCISION (TECHNICAL REPORT)

Task Force on Circumcision

ABSTRACT. Male circumcision consists of the surgical removal of some, or all, of the foreskin (or prepuce) from the penis. It is one of the most common procedures in the world. In the United States, the procedure is commonly performed during the newborn period. In 2007, the American Academy of Pediatrics (AAP) convened a multidisciplinary workgroup of AAP members and other stakeholders to evaluate the evidence regarding male circumcision and update the AAP's 1999 recommendations in this area. The Task Force included AAP representatives from specialty areas as well as members of the AAP Board of Directors and liaisons representing the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention. The Task Force members identified selected topics relevant to male circumcision and conducted a critical review of peer-reviewed literature by using the American Heart Association's template for evidence evaluation.

Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks; furthermore, the benefits of newborn male circumcision justify access to this procedure for families who choose it. Specific benefits from male circumcision were identified for the prevention of urinary tract infections, acquisition of HIV, transmission of some sexually transmitted infections, and penile cancer. Male circumcision does not appear to adversely affect penile sexual function/sensitivity or sexual satisfaction. It is imperative that those providing circumcision are adequately trained and that

both sterile techniques and effective pain management are used. Significant acute complications are rare. In general, untrained providers who perform circumcisions have more complications than well-trained providers who perform the procedure, regardless of whether the former are physicians, nurses, or traditional religious providers.

Parents are entitled to factually correct, nonbiased information about circumcision and should receive this information from clinicians before conception or early in pregnancy, which is when parents typically make circumcision decisions. Parents should determine what is in the best interest of their child. Physicians who counsel families about this decision should provide assistance by explaining the potential benefits and risks and ensuring that parents understand that circumcision is an elective procedure. The Task Force strongly recommends the creation, revision, and enhancement of educational materials to assist parents of male infants with the care of circumcised and uncircumcised penises. The Task Force also strongly recommends the development of educational materials for providers to enhance practitioners' competency in discussing circumcision's benefits and risks with parents.

The Task Force made the following recommendations:

- Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks, and the benefits of newborn male circumcision justify access to this procedure for those families who choose it.
 - Parents are entitled to factually correct, nonbiased information about circumcision that should be provided before conception and early in pregnancy, when parents are most likely to be weighing the option of circumcision of a male child.
 - Physicians counseling families about elective male circumcision should assist parents by explaining, in a nonbiased manner, the potential benefits and risks and by ensuring that they understand the elective nature of the procedure.
 - Parents should weigh the health benefits and risks in light of their own religious, cultural, and personal preferences, as the medical benefits alone may not outweigh these other considerations for individual families.
 - Parents of newborn boys should be instructed in the care of the penis, regardless of whether the newborn has been circumcised or not.
 - Elective circumcision should be performed only if the infant's condition is stable and healthy.
 - Male circumcision should be performed by trained and competent practitioners, by using sterile techniques and effective pain management.
 - Analgesia is safe and effective in reducing the procedural pain associated with newborn circumcision; thus, adequate analgesia should be provided whenever newborn circumcision is performed.
- Nonpharmacologic techniques (eg, positioning, sucrose pacifiers) alone are insufficient to prevent procedural and postprocedural pain and are not recommended as the sole method of analgesia. They

should be used only as analgesic adjuncts to improve infant comfort during circumcision.

- If used, topical creams may cause a higher incidence of skin irritation in low birth weight infants, compared with infants of normal weight; penile nerve block techniques should therefore be chosen for this group of newborns.
 - Key professional organizations (AAP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Society of Anesthesiologists, the American College of Nurse-Midwives, and other midlevel clinicians such as nurse practitioners) should work collaboratively to:
 - Develop standards of trainee proficiency in the performance of anesthetic and procedure techniques, including suturing;
 - Teach the procedure and analgesic techniques during postgraduate training programs;
 - Develop educational materials for clinicians to enhance their own competency in discussing the benefits and risks of circumcision with parents;
 - Offer educational materials to assist parents of male infants with the care of both circumcised and uncircumcised penises.
 - The preventive and public health benefits associated with newborn male circumcision warrant third-party reimbursement of the procedure.
- The American College of Obstetricians and Gynecologists has endorsed this technical report. (8/12)

MALTREATMENT OF CHILDREN WITH DISABILITIES (CLINICAL REPORT)

Roberta A. Hibbard, MD; Larry W. Desch, MD; Committee on Child Abuse and Neglect; and Council on Children With Disabilities

ABSTRACT. Widespread efforts are being made to increase awareness and provide education to pediatricians regarding risk factors of child abuse and neglect. The purpose of this clinical report is to ensure that children with disabilities are recognized as a population that is also at risk of maltreatment. Some conditions related to a disability can be confused with maltreatment. The need for early recognition and intervention of child abuse and neglect in this population, as well as the ways that a medical home can facilitate the prevention and early detection of child maltreatment, are the subject of this report. (5/07, reaffirmed 1/11)

MANAGEMENT OF CHILDREN WITH AUTISM SPECTRUM DISORDERS (CLINICAL REPORT)

Scott M. Myers, MD; Chris Plauché Johnson, MD, MEd; and Council on Children With Disabilities

ABSTRACT. Pediatricians have an important role not only in early recognition and evaluation of autism spectrum disorders but also in chronic management of these disorders. The primary goals of treatment are to maximize the child's ultimate functional independence and quality of life by minimizing the core autism spectrum disorder features, facilitating development and learning, promot-

ing socialization, reducing maladaptive behaviors, and educating and supporting families. To assist pediatricians in educating families and guiding them toward empirically supported interventions for their children, this report reviews the educational strategies and associated therapies that are the primary treatments for children with autism spectrum disorders. Optimization of health care is likely to have a positive effect on habilitative progress, functional outcome, and quality of life; therefore, important issues, such as management of associated medical problems, pharmacologic and nonpharmacologic intervention for challenging behaviors or coexisting mental health conditions, and use of complementary and alternative medical treatments, are also addressed. (11/07, reaffirmed 9/10, 8/14)

MANAGEMENT OF DENTAL TRAUMA IN A PRIMARY CARE SETTING (CLINICAL REPORT)

Martha Ann Keels, DDS, PhD, and Section on Oral Health

ABSTRACT. The American Academy of Pediatrics and its Section on Oral Health have developed this clinical report for pediatricians and primary care physicians regarding the diagnosis, evaluation, and management of dental trauma in children aged 1 to 21 years. This report was developed through a comprehensive search and analysis of the medical and dental literature and expert consensus. Guidelines published and updated by the International Association of Dental Traumatology (www.dentaltrauma-guide.com) are an excellent resource for both dental and nondental health care providers. (1/14)

See full text on page 763.

MANAGEMENT OF FOOD ALLERGY IN THE SCHOOL SETTING (CLINICAL REPORT)

Scott H. Sicherer, MD; Todd Mahr, MD; and Section on Allergy and Immunology

ABSTRACT. Food allergy is estimated to affect approximately 1 in 25 school-aged children and is the most common trigger of anaphylaxis in this age group. School food-allergy management requires strategies to reduce the risk of ingestion of the allergen as well as procedures to recognize and treat allergic reactions and anaphylaxis. The role of the pediatrician or pediatric health care provider may include diagnosing and documenting a potentially life-threatening food allergy, prescribing self-injectable epinephrine, helping the child learn how to store and use the medication in a responsible manner, educating the parents of their responsibility to implement prevention strategies within and outside the home environment, and working with families, schools, and students in developing written plans to reduce the risk of anaphylaxis and to implement emergency treatment in the event of a reaction. This clinical report highlights the role of the pediatrician and pediatric health care provider in managing students with food allergies. (11/10)

MANAGEMENT OF NEONATES WITH SUSPECTED OR PROVEN EARLY-ONSET BACTERIAL SEPSIS (CLINICAL REPORT)

Richard A. Polin, MD, and Committee on Fetus and Newborn

ABSTRACT. With improved obstetrical management and evidence-based use of intrapartum antimicrobial therapy, early-onset neonatal sepsis is becoming less frequent.



However, early-onset sepsis remains one of the most common causes of neonatal morbidity and mortality in the preterm population. The identification of neonates at risk for early-onset sepsis is frequently based on a constellation of perinatal risk factors that are neither sensitive nor specific. Furthermore, diagnostic tests for neonatal sepsis have a poor positive predictive accuracy. As a result, clinicians often treat well-appearing infants for extended periods of time, even when bacterial cultures are negative. The optimal treatment of infants with suspected early-onset sepsis is broad-spectrum antimicrobial agents (ampicillin and an aminoglycoside). Once a pathogen is identified, antimicrobial therapy should be narrowed (unless synergism is needed). Recent data suggest an association between prolonged empirical treatment of preterm infants (≥ 5 days) with broad-spectrum antibiotics and higher risks of late onset sepsis, necrotizing enterocolitis, and mortality. To reduce these risks, antimicrobial therapy should be discontinued at 48 hours in clinical situations in which the probability of sepsis is low. The purpose of this clinical report is to provide a practical and, when possible, evidence-based approach to the management of infants with suspected or proven early-onset sepsis. (4/12)

MANAGEMENT OF PEDIATRIC TRAUMA

Section on Orthopaedics, Committee on Pediatric Emergency Medicine, Section on Critical Care, Section on Surgery, and Section on Transport Medicine (joint with Pediatric Orthopaedic Society of North America)

ABSTRACT. Injury is the number 1 killer of children in the United States. In 2004, injury accounted for 59.5% of all deaths in children younger than 18 years. The financial burden to society of children who survive childhood injury with disability continues to be enormous. The entire process of managing childhood injury is complex and varies by region. Only the comprehensive cooperation of a broadly diverse group of people will have a significant effect on improving the care and outcome of injured children. (4/08, reaffirmed 4/13)

MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN CHILDREN AND

ADOLESCENTS (TECHNICAL REPORT)

Shelley C. Springer, MD, MBA, MSc, JD; Janet Silverstein, MD; Kenneth Copeland, MD; Kelly R. Moore, MD; Greg E. Prazar, MD; Terry Raymer, MD, CDE; Richard N. Shiffman, MD; Vidhu V. Thaker, MD; Meaghan Anderson, MS, RD, LD, CDE; Stephen J. Spann, MD, MBA; and Susan K. Flinn, MA

ABSTRACT. Objective. Over the last 3 decades, the prevalence of childhood obesity has increased dramatically in North America, ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. This technical report describes, in detail, the procedures undertaken to develop the recommendations given in the accompanying clinical practice guideline, "Management of Type 2 Diabetes Mellitus in Children and Adolescents," and provides in-depth information about the rationale for the recommendations and the studies used to make the clinical practice guideline's recommendations.

Methods. A primary literature search was conducted relating to the treatment of T2DM in children and adolescents, and a secondary literature search was conducted relating to the screening and treatment of T2DM's comorbidities in children and adolescents. Inclusion criteria were prospectively and unanimously agreed on by members of the committee. An article was eligible for inclusion if it addressed treatment (primary search) or 1 of 4 comorbidities (secondary search) of T2DM, was published in 1990 or later, was written in English, and included an abstract. Only primary research inquiries were considered; review articles were considered if they included primary data or opinion. The research population had to constitute children and/or adolescents with an existing diagnosis of T2DM; studies of adult patients were considered if at least 10% of the study population was younger than 35 years. All retrieved titles, abstracts, and articles were reviewed by the consulting epidemiologist.

Results. Thousands of articles were retrieved and considered in both searches on the basis of the aforementioned criteria. From those, in the primary search, 199 abstracts were identified for possible inclusion, 58 of which were retained for systematic review. Five of these studies were classified as grade A studies, 1 as grade B, 20 as grade C, and 32 as grade D. Articles regarding treatment of T2DM selected for inclusion were divided into 4 major subcategories on the basis of type of treatment being discussed: (1) medical treatments (32 studies); (2) nonmedical treatments (9 studies); (3) provider behaviors (8 studies); and (4) social issues (9 studies). From the secondary search, an additional 336 abstracts relating to comorbidities were identified for possible inclusion, of which 26 were retained for systematic review. These articles included the following: 1 systematic review of literature regarding comorbidities of T2DM in adolescents; 5 expert opinions presenting global recommendations not based on evidence; 5 cohort studies reporting natural history of disease and comorbidities; 3 with specific attention to comorbidity patterns in specific ethnic groups (case-control, cohort, and clinical report using adult literature); 3 reporting an association between microalbuminuria and retinopathy (2 case-control, 1 cohort); 3 reporting the prevalence of nephropathy (cohort); 1 reporting peripheral vascular disease (case series); 2 discussing retinopathy (1 case-control, 1 position statement); and 3 addressing hyperlipidemia (American Heart Association position statement on cardiovascular risks; American Diabetes Association consensus statement; case series). A breakdown of grade of recommendation shows no grade A studies, 10 grade B studies, 6 grade C studies, and 10 grade D studies. With regard to screening and treatment recommendations for comorbidities, data in children are scarce, and the available literature is conflicting. Therapeutic recommendations for hypertension, dyslipidemia, retinopathy, microalbuminuria, and depression were summarized from expert guideline documents and are presented in detail in the guideline. The references are provided, but the committee did not independently assess the supporting evidence. Screening tools are provided in the Supplemental Information. (1/13)



MARIJUANA: A CONTINUING CONCERN FOR PEDIATRICIANS

Committee on Substance Abuse

ABSTRACT. Marijuana, the common name for products derived from the plant *Cannabis sativa*, is the most common illicit drug used by children and adolescents in the United States. Despite growing concerns by the medical profession about the physical and psychological effects of its active ingredient, Δ -9-tetrahydrocannabinol, survey data continue to show that increasing numbers of young people are using the drug as they become less concerned about its dangers. (10/99, reaffirmed 4/03)

MATERNAL PHENYLKETONURIA

Committee on Genetics

ABSTRACT. Elevated maternal phenylalanine concentrations during pregnancy are teratogenic and may result in growth retardation, microcephaly, significant developmental delays, and birth defects in the offspring of women with poorly controlled phenylketonuria during pregnancy. Women of childbearing age with all forms of phenylketonuria, including mild variants such as mild hyperphenylalaninemia, should receive counseling concerning their risks for adverse fetal effects, optimally before conceiving. The best outcomes occur when strict control of maternal phenylalanine concentration is achieved before conception and continued throughout pregnancy. Included are brief descriptions of novel treatments for phenylketonuria. (8/08, reaffirmed 1/13)

MATERNAL-FETAL INTERVENTION AND FETAL CARE CENTERS (CLINICAL REPORT)

Committee on Bioethics (joint with American College of Obstetricians and Gynecologists Committee on Ethics)

ABSTRACT. The past 2 decades have yielded profound advances in the fields of prenatal diagnosis and fetal intervention. Although fetal interventions are driven by a beneficence-based motivation to improve fetal and neonatal outcomes, advancement in fetal therapies raises ethical issues surrounding maternal autonomy and decision-making, concepts of innovation versus research, and organizational aspects within institutions in the development of fetal care centers. To safeguard the interests of both the pregnant woman and the fetus, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics make recommendations regarding informed consent, the role of research subject advocates and other independent advocates, the availability of support services, the multidisciplinary nature of fetal intervention teams, the oversight of centers, and the need to accumulate maternal and fetal outcome data. (7/11)

MEDIA EDUCATION

Committee on Communications and Media

ABSTRACT. The American Academy of Pediatrics recognizes that exposure to mass media (eg, television, movies, video and computer games, the Internet, music lyrics and videos, newspapers, magazines, books, advertising) presents health risks for children and adolescents but can provide benefits as well. Media education has the potential to reduce the harmful effects of media and accentuate

the positive effects. By understanding and supporting media education, pediatricians can play an important role in reducing harmful effects of media on children and adolescents. (9/10)

MEDIA USE BY CHILDREN YOUNGER THAN 2 YEARS

Council on Communications and Media

ABSTRACT. In 1999, the American Academy of Pediatrics (AAP) issued a policy statement addressing media use in children. The purpose of that statement was to educate parents about the effects that media—both the amount and the content—may have on children. In one part of that statement, the AAP recommended that “pediatricians should urge parents to avoid television viewing for children under the age of two years.” The wording of the policy specifically discouraged media use in this age group, although it is frequently misquoted by media outlets as no media exposure in this age group. The AAP believed that there were significantly more potential negative effects of media than positive ones for this age group and, thus, advised families to thoughtfully consider media use for infants. This policy statement reaffirms the 1999 statement with respect to media use in infants and children younger than 2 years and provides updated research findings to support it. This statement addresses (1) the lack of evidence supporting educational or developmental benefits for media use by children younger than 2 years, (2) the potential adverse health and developmental effects of media use by children younger than 2 years, and (3) diverse effects of parental media use (background media) on children younger than 2 years. (10/11)

MEDIA VIOLENCE

Council on Communications and Media

ABSTRACT. Exposure to violence in media, including television, movies, music, and video games, represents a significant risk to the health of children and adolescents. Extensive research evidence indicates that media violence can contribute to aggressive behavior, desensitization to violence, nightmares, and fear of being harmed. Pediatricians should assess their patients’ level of media exposure and intervene on media-related health risks. Pediatricians and other child health care providers can advocate for a safer media environment for children by encouraging media literacy, more thoughtful and proactive use of media by children and their parents, more responsible portrayal of violence by media producers, and more useful and effective media ratings. Office counseling has been shown to be effective. (10/09)

MEDICAID POLICY STATEMENT

Committee on Child Health Financing

ABSTRACT. Medicaid insures 39% of the children in the United States. This revision of the 2005 Medicaid Policy Statement of the American Academy of Pediatrics reflects opportunities for changes in state Medicaid programs resulting from the 2010 Patient Protection and Affordable Care Act as upheld in 2012 by the Supreme Court. Policy recommendations focus on the areas of benefit coverage, financing and payment, eligibility, outreach and enrollment, managed care, and quality improvement. (4/13)

MEDICAL CONCERNS IN THE FEMALE ATHLETE*Committee on Sports Medicine and Fitness*

ABSTRACT. Female children and adolescents who participate regularly in sports may develop certain medical conditions, including disordered eating, menstrual dysfunction, and decreased bone mineral density. The pediatrician can play an important role in monitoring the health of young female athletes. This revised policy statement provides updated and expanded information for pediatricians on these health concerns as well as recommendations for evaluation, treatment, and ongoing assessments of female athletes. (9/00, reaffirmed 5/05, 5/08)

MEDICAL CONDITIONS AFFECTING SPORTS PARTICIPATION (CLINICAL REPORT)*Stephen G. Rice, MD, PhD, MPH, and Council on Sports Medicine and Fitness*

ABSTRACT. Children and adolescents with medical conditions present special issues with respect to participation in athletic activities. The pediatrician can play an important role in determining whether a child with a health condition should participate in certain sports by assessing the child's health status, suggesting appropriate equipment or modifications of sports to decrease the risk of injury, and educating the athlete, parent(s) or guardian, and coach regarding the risks of injury as they relate to the child's condition. This report updates a previous policy statement and provides information for pediatricians on sports participation for children and adolescents with medical conditions. (4/08, reaffirmed 5/11, 6/14)

MEDICAL EMERGENCIES OCCURRING AT SCHOOL*Council on School Health*

ABSTRACT. Children and adults might experience medical emergency situations because of injuries, complications of chronic health conditions, or unexpected major illnesses that occur in schools. In February 2001, the American Academy of Pediatrics issued a policy statement titled "Guidelines for Emergency Medical Care in Schools" (available at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/2/435>). Since the release of that statement, the spectrum of potential individual student emergencies has changed significantly. The increase in the number of children with special health care needs and chronic medical conditions attending schools and the challenges associated with ensuring that schools have access to on-site licensed health care professionals on an ongoing basis have added to increasing the risks of medical emergencies in schools. The goal of this statement is to increase pediatricians' awareness of schools' roles in preparing for individual student emergencies and to provide recommendations for primary care and school physicians on how to assist and support school personnel. (10/08, reaffirmed 9/11)

THE MEDICAL HOME*Medical Home Initiatives for Children With Special Needs Project Advisory Committee (7/02, reaffirmed 5/08)***MEDICAL STAFF APPOINTMENT AND DELINEATION OF PEDIATRIC PRIVILEGES IN HOSPITALS (CLINICAL REPORT)***Daniel A. Rauch, MD; Committee on Hospital Care; and Section on Hospital Medicine*

ABSTRACT. The review and verification of credentials and the granting of clinical privileges are required of every hospital to ensure that members of the medical staff are competent and qualified to provide specified levels of patient care. The credentialing process involves the following: (1) assessment of the professional and personal background of each practitioner seeking privileges; (2) assignment of privileges appropriate for the clinician's training and experience; (3) ongoing monitoring of the professional activities of each staff member; and (4) periodic reappointment to the medical staff on the basis of objectively measured performance. We examine the essential elements of a credentials review for initial and renewed medical staff appointments along with suggested criteria for the delineation of clinical privileges. Sample forms for the delineation of privileges can be found on the American Academy of Pediatrics Committee on Hospital Care Web site (<http://www.aap.org/visit/cmt19.htm>). Because of differences among individual hospitals, no 1 method for credentialing is universally applicable. The medical staff of each hospital must, therefore, establish its own process based on the general principles reviewed in this report. The issues of medical staff membership and credentialing have become very complex, and institutions and medical staffs are vulnerable to legal action. Consequently, it is advisable for hospitals and medical staffs to obtain expert legal advice when medical staff bylaws are constructed or revised. (3/12)

MENINGOCOCCAL CONJUGATE VACCINES POLICY UPDATE: BOOSTER DOSE RECOMMENDATIONS*Committee on Infectious Diseases*

ABSTRACT. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics approved updated recommendations for the use of quadravalent (serogroups A, C, W-135, and Y) meningococcal conjugate vaccines (Menactra [Sanofi Pasteur, Swiftwater, PA] and Menveo [Novartis, Basel, Switzerland]) in adolescents and in people at persistent high risk of meningococcal disease. The recommendations supplement previous Advisory Committee on Immunization Practices and American Academy of Pediatrics recommendations for meningococcal vaccinations. Data were reviewed pertaining to immunogenicity in high-risk groups, bactericidal antibody persistence after immunization, current epidemiology of meningococcal disease, meningococcal conjugate vaccine effectiveness, and cost-effectiveness of different strategies for vaccination of adolescents. This review prompted the following recommendations: (1) adolescents should be routinely immunized at 11 through 12 years of age and given a booster dose at 16 years of age; (2) adolescents who received their first dose at age 13 through 15 years should receive a booster at age 16 through 18 years or up to 5 years after their first dose; (3) adolescents who receive their first dose of meningococcal conjugate vaccine at or after 16 years of age do not need a booster dose; (4) a 2-dose

primary series should be administered 2 months apart for those who are at increased risk of invasive meningococcal disease because of persistent complement component (eg, C5–C9, properdin, factor H, or factor D) deficiency (9 months through 54 years of age) or functional or anatomic asplenia (2–54 years of age) and for adolescents with HIV infection; and (5) a booster dose should be given 3 years after the primary series if the primary 2-dose series was given from 2 through 6 years of age and every 5 years for persons whose 2-dose primary series or booster dose was given at 7 years of age or older who are at risk of invasive meningococcal disease because of persistent component (eg, C5–C9, properdin, factor H, or factor D) deficiency or functional or anatomic asplenia. (11/11)

MENSTRUATION IN GIRLS AND ADOLESCENTS: USING THE MENSTRUAL CYCLE AS A VITAL SIGN (CLINICAL REPORT)

Committee on Adolescence (joint with American College of Obstetricians and Gynecologists Committee on Adolescent Health Care)

ABSTRACT. Young patients and their parents often are unsure about what represents normal menstrual patterns, and clinicians also may be unsure about normal ranges for menstrual cycle length and amount and duration of flow through adolescence. It is important to be able to educate young patients and their parents regarding what to expect of a first period and about the range for normal cycle length of subsequent menses. It is equally important for clinicians to have an understanding of bleeding patterns in girls and adolescents, the ability to differentiate between normal and abnormal menstruation, and the skill to know how to evaluate young patients' conditions appropriately. Using the menstrual cycle as an additional vital sign adds a powerful tool to the assessment of normal development and the exclusion of pathological conditions. (11/06)

MINORS AS LIVING SOLID-ORGAN DONORS (CLINICAL REPORT)

Lainie Friedman Ross, MD, PhD; J. Richard Thistlethwaite Jr, MD, PhD; and Committee on Bioethics

ABSTRACT. In the past half-century, solid-organ transplantation has become standard treatment for a variety of diseases in children and adults. The major limitation for all transplantation is the availability of donors, and the gap between demand and supply continues to grow despite the increase in living donors. Although rare, children do serve as living donors, and these donations raise serious ethical issues. This clinical report includes a discussion of the ethical considerations regarding minors serving as living donors, using the traditional benefit/burden calculus from the perspectives of both the donor and the recipient. The report also includes an examination of the circumstances under which a minor may morally participate as a living donor, how to minimize risks, and what the informed-consent process should entail. The American Academy of Pediatrics holds that minors can morally serve as living organ donors but only in exceptional circumstances when specific criteria are fulfilled. (8/08, reaffirmed 5/11)

MODEL CONTRACTUAL LANGUAGE FOR MEDICAL NECESSITY FOR CHILDREN

Committee on Child Health Financing

ABSTRACT. The term "medical necessity" is used by Medicare and Medicaid and in insurance contracts to refer to medical services that are generally recognized as appropriate for the diagnosis, prevention, or treatment of disease and injury. There is no consensus on how to define and apply the term and the accompanying rules and regulations, and as a result there has been substantial variation in medical-necessity definitions and interpretations. With this policy statement, the American Academy of Pediatrics hopes to encourage insurers to adopt more consistent medical-necessity definitions that take into account the needs of children. (7/05, reaffirmed 10/11)

MOLECULAR GENETIC TESTING IN PEDIATRIC PRACTICE: A SUBJECT REVIEW (CLINICAL REPORT)

Committee on Genetics

ABSTRACT. Although many types of diagnostic and carrier testing for genetic disorders have been available for decades, the use of molecular methods is a relatively recent phenomenon. Such testing has expanded the range of disorders that can be diagnosed and has enhanced the ability of clinicians to provide accurate prognostic information and institute appropriate health supervision measures. However, the proper application of these tests may be difficult because of their scientific complexity and the potential for negative, sometimes unexpected, consequences for many patients. The purposes of this subject review are to provide background information on molecular genetic tests, to describe specific testing modalities, and to discuss some of the benefits and risks specific to the pediatric population. It is likely that pediatricians will use these testing methods increasingly for their patients and will need to evaluate critically their diagnostic and prognostic implications. (12/00, reaffirmed 5/07)

MOTOR DELAYS: EARLY IDENTIFICATION AND EVALUATION (CLINICAL REPORT)

Garey H. Noritz, MD; Nancy A. Murphy, MD; and Neuromotor Screening Expert Panel

ABSTRACT. Pediatricians often encounter children with delays of motor development in their clinical practices. Earlier identification of motor delays allows for timely referral for developmental interventions as well as diagnostic evaluations and treatment planning. A multidisciplinary expert panel developed an algorithm for the surveillance and screening of children for motor delays within the medical home, offering guidance for the initial workup and referral of the child with possible delays in motor development. Highlights of this clinical report include suggestions for formal developmental screening at the 9-, 18-, 30-, and 48-month well-child visits; approaches to the neurologic examination, with emphasis on the assessment of muscle tone; and initial diagnostic approaches for medical home providers. Use of diagnostic tests to evaluate children with motor delays are described, including brain MRI for children with high muscle tone, and measuring serum creatine kinase concentration of those with decreased muscle tone. The importance of

pursuing diagnostic tests while concurrently referring patients to early intervention programs is emphasized. (5/13)

NEONATAL DRUG WITHDRAWAL (CLINICAL REPORT)

Mark L. Hudak, MD; Rosemarie C. Tan, MD, PhD;

Committee on Drugs; and Committee on Fetus and Newborn

ABSTRACT. Maternal use of certain drugs during pregnancy can result in transient neonatal signs consistent with withdrawal or acute toxicity or cause sustained signs consistent with a lasting drug effect. In addition, hospitalized infants who are treated with opioids or benzodiazepines to provide analgesia or sedation may be at risk for manifesting signs of withdrawal. This statement updates information about the clinical presentation of infants exposed to intrauterine drugs and the therapeutic options for treatment of withdrawal and is expanded to include evidence-based approaches to the management of the hospitalized infant who requires weaning from analgesics or sedatives. (1/12)

THE NEW MORBIDITY REVISITED: A RENEWED COMMITMENT TO THE PSYCHOSOCIAL ASPECTS OF PEDIATRIC CARE

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. In 1993, the American Academy of Pediatrics adopted the policy statement "The Pediatrician and the 'New Morbidity.'" Since then, social difficulties, behavioral problems, and developmental difficulties have become a main part of the scope of pediatric practice, and recognition of the importance of these areas has increased. This statement reaffirms the Academy's commitment to prevention, early detection, and management of behavioral, developmental, and social problems as a focus in pediatric practice. (11/01)

NEWBORN SCREENING EXPANDS: RECOMMENDATIONS FOR PEDIATRICIANS AND MEDICAL HOMES—IMPLICATIONS FOR THE SYSTEM (CLINICAL REPORT)

Newborn Screening Authoring Committee

ABSTRACT. Advances in newborn screening technology, coupled with recent advances in the diagnosis and treatment of rare but serious congenital conditions that affect newborn infants, provide increased opportunities for positively affecting the lives of children and their families. These advantages also pose new challenges to primary care pediatricians, both educationally and in response to the management of affected infants. Primary care pediatricians require immediate access to clinical and diagnostic information and guidance and have a proactive role to play in supporting the performance of the newborn screening system. Primary care pediatricians must develop office policies and procedures to ensure that newborn screening is conducted and that results are transmitted to them in a timely fashion; they must also develop strategies to use should these systems fail. In addition, collaboration with local, state, and national partners is essential for promoting actions and policies that will optimize the function of

the newborn screening systems and ensure that families receive the full benefit of them. (1/08)

NEWBORN SCREENING FACT SHEETS, INTRODUCTION TO THE (TECHNICAL REPORT)

Celia I. Kaye, MD, PhD, and Committee on Genetics

ABSTRACT. Newborn screening fact sheets were last revised in 1996 by the Committee on Genetics of the American Academy of Pediatrics. These fact sheets have been revised again because of advances in the field, including technologic innovations such as tandem mass spectrometry, as well as greater appreciation of ethical issues such as informed consent. The fact sheets provide information to assist pediatricians and other professionals who care for children in performing their essential role within the newborn screening public health system. The newborn screening system consists of 5 parts: (1) newborn testing; (2) follow-up of abnormal screening results to facilitate timely diagnostic testing and management; (3) diagnostic testing; (4) disease management, which requires coordination with the medical home and genetic counseling; and (5) continuous evaluation and improvement of the newborn screening system. The following disorders are reviewed in the newborn screening fact sheets (which are available at www.pediatrics.org/cgi/content/full/118/3/e934): biotinidase deficiency, congenital adrenal hyperplasia, congenital hearing loss, congenital hypothyroidism, cystic fibrosis, galactosemia, homocystinuria, maple syrup urine disease, medium-chain acyl-coenzyme A dehydrogenase deficiency, phenylketonuria, sickle cell disease and other hemoglobinopathies, and tyrosinemia. (9/06, reaffirmed 1/11)

NEWBORN SCREENING FACT SHEETS (TECHNICAL REPORT)

Celia I. Kaye, MD, PhD, and Committee on Genetics

ABSTRACT. Newborn screening fact sheets were last revised in 1996 by the American Academy of Pediatrics Committee on Genetics. This revision was prompted by advances in the field since 1996, including technologic innovations, as well as greater appreciation of ethical issues such as those surrounding informed consent. The following disorders are discussed in this revision of the newborn screening fact sheets: biotinidase deficiency, congenital adrenal hyperplasia, congenital hearing loss, congenital hypothyroidism, cystic fibrosis, galactosemia, homocystinuria, maple syrup urine disease, medium-chain acyl-coenzyme A dehydrogenase deficiency, phenylketonuria, sickle cell disease and other hemoglobinopathies, and tyrosinemia. A series of topics related to newborn screening is discussed in a companion publication to this electronic publication of the fact sheets (available at: www.pediatrics.org/cgi/content/full/118/3/1304). These topics are newborn screening as a public health system; factors contributing to the need for review of the newborn screening system; informed consent; tandem mass spectrometry; DNA analysis in newborn screening; status of newborn screening in the United States; and the effect of sample timing, preterm birth, diet, transfusion, and total parenteral nutrition on newborn screening results. (9/06, reaffirmed 1/11)



NONDISCRIMINATION IN PEDIATRIC HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. This policy statement is a revision of a 2001 statement and articulates the positions of the American Academy of Pediatrics on nondiscrimination in pediatric health care. It addresses both pediatricians who provide health care and the infants, children, adolescents, and young adults whom they serve. (10/07, reaffirmed 6/11)

NONINITIATION OR WITHDRAWAL OF INTENSIVE CARE FOR HIGH-RISK NEWBORNS

Committee on Fetus and Newborn

ABSTRACT. Advances in medical technology have led to dilemmas in initiation and withdrawal of intensive care of newborn infants with a very poor prognosis. Physicians and parents together must make difficult decisions guided by their understanding of the child's best interest. The foundation for these decisions consists of several key elements: (1) direct and open communication between the health care team and the parents of the child with regard to the medical status, prognosis, and treatment options; (2) inclusion of the parents as active participants in the decision process; (3) continuation of comfort care even when intensive care is not being provided; and (4) treatment decisions that are guided primarily by the best interest of the child. (2/07, reaffirmed 5/10)

NONORAL FEEDING FOR CHILDREN AND YOUTH WITH DEVELOPMENTAL OR ACQUIRED DISABILITIES (CLINICAL REPORT)

Richard C. Adams, MD, FAAP; Ellen Roy Elias, MD, FAAP; and Council on Children With Disabilities

ABSTRACT. The decision to initiate enteral feedings is multifaceted, involving medical, financial, cultural, and emotional considerations. Children who have developmental or acquired disabilities are at risk for having primary and secondary conditions that affect growth and nutritional well-being. This clinical report provides (1) an overview of clinical issues in children who have developmental or acquired disabilities that may prompt a need to consider nonoral feedings, (2) a systematic way to support the child and family in clinical decisions related to initiating nonoral feeding, (3) information on surgical options that the family may need to consider in that decision-making process, and (4) pediatric guidance for ongoing care after initiation of nonoral feeding intervention, including care of the gastrostomy tube and skin site. Ongoing medical and psychosocial support is needed after initiation of nonoral feedings and is best provided through the collaborative efforts of the family and a team of professionals that may include the pediatrician, dietitian, social worker, and/or therapists. (11/14)

See full text on page 777.

NONTHERAPEUTIC USE OF ANTIMICROBIAL AGENTS IN ANIMAL AGRICULTURE: IMPLICATIONS FOR PEDIATRICS (TECHNICAL REPORT)

Committee on Environmental Health and Committee on Infectious Diseases

ABSTRACT. Antimicrobial resistance is widespread. Overuse or misuse of antimicrobial agents in veterinary and human medicine is responsible for increasing the crisis of resistance to antimicrobial agents. The American

Academy of Pediatrics, in conjunction with the US Public Health Service, has begun to address this problem by disseminating policies on the judicious use of antimicrobial agents in humans. Between 40% and 80% of the antimicrobial agents used in the United States each year are used in food animals; many are identical or very similar to drugs used in humans. Most of this use involves the addition of low doses of antimicrobial agents to the feed of healthy animals over prolonged periods to promote growth and increase feed efficiency or at a range of doses to prevent disease. These nontherapeutic uses contribute to resistance and create health dangers for humans. This report will describe how antimicrobial agents are used in animal agriculture and review the mechanisms by which such uses contribute to resistance in human pathogens. Although therapeutic use of antimicrobial agents in agriculture clearly contributes to the development of resistance, this report will concentrate on nontherapeutic uses in healthy animals. (9/04, reaffirmed 10/08, 4/13)

OFFICE-BASED CARE FOR LESBIAN, GAY, BISEXUAL, TRANSGENDER, AND QUESTIONING YOUTH

Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics issued its last statement on homosexuality and adolescents in 2004. Although most lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth are quite resilient and emerge from adolescence as healthy adults, the effects of homophobia and heterosexism can contribute to health disparities in mental health with higher rates of depression and suicidal ideation, higher rates of substance abuse, and more sexually transmitted and HIV infections. Pediatricians should have offices that are teen-friendly and welcoming to sexual minority youth. Obtaining a comprehensive, confidential, developmentally appropriate adolescent psychosocial history allows for the discovery of strengths and assets as well as risks. Referrals for mental health or substance abuse may be warranted. Sexually active LGBTQ youth should have sexually transmitted infection/HIV testing according to recommendations of the Sexually Transmitted Diseases Treatment Guidelines of the Centers for Disease Control and Prevention based on sexual behaviors. With appropriate assistance and care, sexual minority youth should live healthy, productive lives while transitioning through adolescence and young adulthood. (6/13)

OFFICE-BASED CARE FOR LESBIAN, GAY, BISEXUAL, TRANSGENDER, AND QUESTIONING YOUTH (TECHNICAL REPORT)

David A. Levine, MD, and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics issued its last statement on homosexuality and adolescents in 2004. This technical report reflects the rapidly expanding medical and psychosocial literature about sexual minority youth. Pediatricians should be aware that some youth in their care may have concerns or questions about their sexual orientation or that of siblings, friends, parents, relatives, or others and should provide factual, current, nonjudgmental information in a confidential manner. Although most lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth are quite resilient and

emerge from adolescence as healthy adults, the effects of homophobia and heterosexism can contribute to increased mental health issues for sexual minority youth. LGBTQ and MSM/WSW (men having sex with men and women having sex with women) adolescents, in comparison with heterosexual adolescents, have higher rates of depression and suicidal ideation, higher rates of substance abuse, and more risky sexual behaviors. Obtaining a comprehensive, confidential, developmentally appropriate adolescent psychosocial history allows for the discovery of strengths and assets as well as risks. Pediatricians should have offices that are teen-friendly and welcoming to sexual minority youth. This includes having supportive, engaging office staff members who ensure that there are no barriers to care. For transgender youth, pediatricians should provide the opportunity to acknowledge and affirm their feelings of gender dysphoria and desires to transition to the opposite gender. Referral of transgender youth to a qualified mental health professional is critical to assist with the dysphoria, to educate them, and to assess their readiness for transition. With appropriate assistance and care, sexual minority youth should live healthy, productive lives while transitioning through adolescence and young adulthood. (6/13)

OFFICE-BASED COUNSELING FOR UNINTENTIONAL INJURY PREVENTION (CLINICAL REPORT)

H. Garry Gardner, MD, and Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Unintentional injuries are the leading cause of death for children older than 1 year. Pediatricians should include unintentional injury prevention as a major component of anticipatory guidance for infants, children, and adolescents. The content of injury-prevention counseling varies for infants, preschool-aged children, school-aged children, and adolescents. This report provides guidance on the content of unintentional injury-prevention counseling for each of those age groups. (1/07)

OFF-LABEL USE OF DRUGS IN CHILDREN

Committee on Drugs

ABSTRACT. The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than 500 labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. (2/14)

See full text on page 797.

OPHTHALMOLOGIC EXAMINATIONS IN CHILDREN WITH JUVENILE RHEUMATOID ARTHRITIS (CLINICAL REPORT)

James Cassidy, MD; Jane Kirolin, MD; Carol Lindsley, MD; James Nocton, MD; Section on Rheumatology; and Section on Ophthalmology

ABSTRACT. Unlike the joints, ocular involvement with juvenile rheumatoid arthritis is most often asymptomatic; yet, the inflammation can cause serious morbidity with loss of vision. Scheduled slit-lamp examinations by an ophthalmologist at specific intervals can detect ocular disease early, and prompt treatment can prevent vision loss. (5/06)

OPTIMIZING BONE HEALTH IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Neville H. Golden, MD; Steven A. Abrams, MD; and Committee on Nutrition

ABSTRACT. The pediatrician plays a major role in helping optimize bone health in children and adolescents. This clinical report reviews normal bone acquisition in infants, children, and adolescents and discusses factors affecting bone health in this age group. Previous recommended daily allowances for calcium and vitamin D are updated, and clinical guidance is provided regarding weight-bearing activities and recommendations for calcium and vitamin D intake and supplementation. Routine calcium supplementation is not recommended for healthy children and adolescents, but increased dietary intake to meet daily requirements is encouraged. The American Academy of Pediatrics endorses the higher recommended dietary allowances for vitamin D advised by the Institute of Medicine and supports testing for vitamin D deficiency in children and adolescents with conditions associated with increased bone fragility. Universal screening for vitamin D deficiency is not routinely recommended in healthy children or in children with dark skin or obesity because there is insufficient evidence of the cost-benefit of such a practice in reducing fracture risk. The preferred test to assess bone health is dual-energy x-ray absorptiometry, but caution is advised when interpreting results in children and adolescents who may not yet have achieved peak bone mass. For analyses, z scores should be used instead of T scores, and corrections should be made for size. Office-based strategies for the pediatrician to optimize bone health are provided. This clinical report has been endorsed by American Bone Health. (9/14)

See full text on page 805.

ORAL AND DENTAL ASPECTS OF CHILD ABUSE AND NEGLECT (CLINICAL REPORT)

Nancy Kellogg, MD, and Committee on Child Abuse and Neglect (joint with American Academy of Pediatric Dentistry)

ABSTRACT. In all 50 states, physicians and dentists are required to report suspected cases of abuse and neglect to social service or law enforcement agencies. The purpose of this report is to review the oral and dental aspects of physical and sexual abuse and dental neglect and the role of physicians and dentists in evaluating such conditions. This report addresses the evaluation of bite marks

as well as perioral and intraoral injuries, infections, and diseases that may cause suspicion for child abuse or neglect. Physicians receive minimal training in oral health and dental injury and disease and, thus, may not detect dental aspects of abuse or neglect as readily as they do child abuse and neglect involving other areas of the body. Therefore, physicians and dentists are encouraged to collaborate to increase the prevention, detection, and treatment of these conditions. (12/05, reaffirmed 1/09, 1/14)

ORAL HEALTH CARE FOR CHILDREN WITH DEVELOPMENTAL DISABILITIES (CLINICAL REPORT)

Kenneth W. Norwood, Jr, MD; Rebecca L. Slayton, DDS, PhD; Council on Children With Disabilities; and Section on Oral Health

ABSTRACT. Children with developmental disabilities often have unmet complex health care needs as well as significant physical and cognitive limitations. Children with more severe conditions and from low-income families are particularly at risk with high dental needs and poor access to care. In addition, children with developmental disabilities are living longer, requiring continued oral health care. This clinical report describes the effect that poor oral health has on children with developmental disabilities as well as the importance of partnerships between the pediatric medical and dental homes. Basic knowledge of the oral health risk factors affecting children with developmental disabilities is provided. Pediatricians may use the report to guide their incorporation of oral health assessments and education into their well-child examinations for children with developmental disabilities. This report has medical, legal, educational, and operational implications for practicing pediatricians. (2/13)

ORAL HEALTH RISK ASSESSMENT TIMING AND ESTABLISHMENT OF THE DENTAL HOME

Section on Pediatric Dentistry

ABSTRACT. Early childhood dental caries has been reported by the Centers for Disease Control and Prevention to be perhaps the most prevalent infectious disease of our nation's children. Early childhood dental caries occurs in all racial and socioeconomic groups; however, it tends to be more prevalent in low-income children, in whom it occurs in epidemic proportions. Dental caries results from an overgrowth of specific organisms that are a part of normally occurring human flora. Human dental flora is site specific, and an infant is not colonized until the eruption of the primary dentition at approximately 6 to 30 months of age. The most likely source of inoculation of an infant's dental flora is the mother or another intimate care provider, through shared utensils, etc. Decreasing the level of cariogenic organisms in the mother's dental flora at the time of colonization can significantly impact the child's predisposition to caries. To prevent caries in children, high-risk individuals must be identified at an early age (preferably high-risk mothers during prenatal care), and aggressive strategies should be adopted, including anticipatory guidance, behavior modifications (oral hygiene and feeding practices), and establishment of a dental home by 1 year of age for children deemed at risk. (5/03, reaffirmed 5/09)

ORGANIC FOODS: HEALTH AND ENVIRONMENTAL ADVANTAGES AND DISADVANTAGES (CLINICAL REPORT)

Joel Forman, MD; Janet Silverstein, MD; Committee on Nutrition; and Council on Environmental Health

ABSTRACT. The US market for organic foods has grown from \$3.5 billion in 1996 to \$28.6 billion in 2010, according to the Organic Trade Association. Organic products are now sold in specialty stores and conventional supermarkets. Organic products contain numerous marketing claims and terms, only some of which are standardized and regulated.

In terms of health advantages, organic diets have been convincingly demonstrated to expose consumers to fewer pesticides associated with human disease. Organic farming has been demonstrated to have less environmental impact than conventional approaches. However, current evidence does not support any meaningful nutritional benefits or deficits from eating organic compared with conventionally grown foods, and there are no well-powered human studies that directly demonstrate health benefits or disease protection as a result of consuming an organic diet. Studies also have not demonstrated any detrimental or disease-promoting effects from an organic diet. Although organic foods regularly command a significant price premium, well-designed farming studies demonstrate that costs can be competitive and yields comparable to those of conventional farming techniques. Pediatricians should incorporate this evidence when discussing the health and environmental impact of organic foods and organic farming while continuing to encourage all patients and their families to attain optimal nutrition and dietary variety consistent with the US Department of Agriculture's MyPlate recommendations.

This clinical report reviews the health and environmental issues related to organic food production and consumption. It defines the term "organic," reviews organic food-labeling standards, describes organic and conventional farming practices, and explores the cost and environmental implications of organic production techniques. It examines the evidence available on nutritional quality and production contaminants in conventionally produced and organic foods. Finally, this report provides guidance for pediatricians to assist them in advising their patients regarding organic and conventionally produced food choices. (10/12)

ORGANIZED SPORTS FOR CHILDREN AND PREADOLESCENTS

Committee on Sports Medicine and Fitness and Committee on School Health

ABSTRACT. Participation in organized sports provides an opportunity for young people to increase their physical activity and develop physical and social skills. However, when the demands and expectations of organized sports exceed the maturation and readiness of the participant, the positive aspects of participation can be negated. The nature of parental or adult involvement can also influence the degree to which participation in organized sports is a positive experience for preadolescents. This updates a previous policy statement on athletics for preadolescents and incorporates guidelines for sports participation for

preschool children. Recommendations are offered on how pediatricians can help determine a child's readiness to participate, how risks can be minimized, and how child-oriented goals can be maximized. (6/01, reaffirmed 1/05, 6/11)

OUT-OF-HOME PLACEMENT FOR CHILDREN AND ADOLESCENTS WITH DISABILITIES (CLINICAL REPORT)

Sandra L. Friedman, MD, MPH; Miriam A. Kalichman, MD; and Council on Children With Disabilities

ABSTRACT. The vast majority of children and youth with chronic and complex health conditions who also have intellectual and developmental disabilities are cared for in their homes. Social, legal, policy, and medical changes through the years have allowed for an increase in needed support within the community. However, there continues to be a relatively small group of children who live in various types of congregate care settings. This clinical report describes these settings and the care and services that are provided in them. The report also discusses reasons families choose out-of-home placement for their children, barriers to placement, and potential effects of this decision on family members. We examine the pediatrician's role in caring for children with severe intellectual and developmental disabilities and complex medical problems in the context of responding to parental inquiries about out-of-home placement and understanding factors affecting these types of decisions. Common medical problems and care issues for children residing outside the family home are reviewed. Variations in state and federal regulations, challenges in understanding local systems, and access to services are also discussed. (9/14)

See full text on page 823.

OUT-OF-SCHOOL SUSPENSION AND EXPULSION

Council on School Health

ABSTRACT. The primary mission of any school system is to educate students. To achieve this goal, the school district must maintain a culture and environment where all students feel safe, nurtured, and valued and where order and civility are expected standards of behavior. Schools cannot allow unacceptable behavior to interfere with the school district's primary mission. To this end, school districts adopt codes of conduct for expected behaviors and policies to address unacceptable behavior. In developing these policies, school boards must weigh the severity of the offense and the consequences of the punishment and the balance between individual and institutional rights and responsibilities. Out-of-school suspension and expulsion are the most severe consequences that a school district can impose for unacceptable behavior. Traditionally, these consequences have been reserved for offenses deemed especially severe or dangerous and/or for recalcitrant offenders. However, the implications and consequences of out-of-school suspension and expulsion and "zero-tolerance" are of such severity that their application and appropriateness for a developing child require periodic review. The indications and effectiveness of exclusionary discipline policies that demand automatic or rigorous application are increasingly questionable. The impact of these policies on offenders, other children, school districts, and communities is broad. Periodic scru-

tiny of policies should be placed not only on the need for a better understanding of the educational, emotional, and social impact of out-of-school suspension and expulsion on the individual student but also on the greater societal costs of such rigid policies. Pediatricians should be prepared to assist students and families affected by out-of-school suspension and expulsion and should be willing to guide school districts in their communities to find more effective and appropriate alternatives to exclusionary discipline policies for the developing child. A discussion of preventive strategies and alternatives to out-of-school suspension and expulsion, as well as recommendations for the role of the physician in matters of out-of-school suspension and expulsion are included. School-wide positive behavior support/positive behavior intervention and support is discussed as an effective alternative. (2/13)

OVERCROWDING CRISIS IN OUR NATION'S EMERGENCY DEPARTMENTS: IS OUR SAFETY NET UNRAVELING?

Committee on Pediatric Emergency Medicine

ABSTRACT. Emergency departments (EDs) are a vital component in our health care safety net, available 24 hours a day, 7 days a week, for all who require care. There has been a steady increase in the volume and acuity of patient visits to EDs, now with well over 100 million Americans (30 million children) receiving emergency care annually. This rise in ED utilization has effectively saturated the capacity of EDs and emergency medical services in many communities. The resulting phenomenon, commonly referred to as ED overcrowding, now threatens access to emergency services for those who need them the most. As managers of the pediatric medical home and advocates for children and optimal pediatric health care, there is a very important role for pediatricians and the American Academy of Pediatrics in guiding health policy decision-makers toward effective solutions that promote the medical home and timely access to emergency care. (9/04, reaffirmed 5/07, 6/11)

OVERUSE INJURIES, OVERTRAINING, AND BURNOUT IN CHILD AND ADOLESCENT ATHLETES (CLINICAL REPORT)

Joel S. Brenner, MD, MPH, and Council on Sports Medicine and Fitness

ABSTRACT. Overuse is one of the most common etiologic factors that lead to injuries in the pediatric and adolescent athlete. As more children are becoming involved in organized and recreational athletics, the incidence of overuse injuries is increasing. Many children are participating in sports year-round and sometimes on multiple teams simultaneously. This overtraining can lead to burnout, which may have a detrimental effect on the child participating in sports as a lifelong healthy activity. One contributing factor to overtraining may be parental pressure to compete and succeed. The purpose of this clinical report is to assist pediatricians in identifying and counseling at-risk children and their families. This report supports the American Academy of Pediatrics policy statement on intensive training and sport specialization. (6/07, reaffirmed 3/11, 6/14)

PALLIATIVE CARE FOR CHILDREN

Committee on Bioethics and Committee on Hospital Care

ABSTRACT. This statement presents an integrated model for providing palliative care for children living with a life-threatening or terminal condition. Advice on the development of a palliative care plan and on working with parents and children is also provided. Barriers to the provision of effective pediatric palliative care and potential solutions are identified. The American Academy of Pediatrics recommends the development and broad availability of pediatric palliative care services based on child-specific guidelines and standards. Such services will require widely distributed and effective palliative care education of pediatric health care professionals. The Academy offers guidance on responding to requests for hastening death, but does not support the practice of physician-assisted suicide or euthanasia for children. (8/00, reaffirmed 6/03, 10/06, 2/12)

PARENT-PROVIDER-COMMUNITY PARTNERSHIPS: OPTIMIZING OUTCOMES FOR CHILDREN WITH DISABILITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Paul S. Carbone, MD; and Council on Children With Disabilities

ABSTRACT. Children with disabilities and their families have multifaceted medical, developmental, educational, and habilitative needs that are best addressed through strong partnerships among parents, providers, and communities. However, traditional health care systems are designed to address acute rather than chronic conditions. Children with disabilities require high-quality medical homes that provide care coordination and transitional care, and their families require social and financial supports. Integrated community systems of care that promote participation of all children are needed. The purpose of this clinical report is to explore the challenges of developing effective community-based systems of care and to offer suggestions to pediatricians and policy-makers regarding the development of partnerships among children with disabilities, their families, and health care and other providers to maximize health and well-being of these children and their families. (9/11)

PARENTAL LEAVE FOR RESIDENTS AND PEDIATRIC TRAINING PROGRAMS

Section on Medical Students, Residents, and Fellowship

Trainees and Committee on Early Childhood

ABSTRACT. The American Academy of Pediatrics (AAP) is committed to the development of rational, equitable, and effective parental leave policies that are sensitive to the needs of pediatric residents, families, and developing infants and that enable parents to spend adequate and good-quality time with their young children. It is important for each residency program to have a policy for parental leave that is written, that is accessible to residents, and that clearly delineates program practices regarding parental leave. At a minimum, a parental leave policy for residents and fellows should conform legally with the Family Medical Leave Act as well as with respective state laws and should meet institutional requirements of the Accreditation Council for Graduate Medical Education for accredited programs. Policies should be well formulated

and communicated in a culturally sensitive manner. The AAP advocates for extension of benefits consistent with the Family Medical Leave Act to all residents and interns beginning at the time that pediatric residency training begins. The AAP recommends that regardless of gender, residents who become parents should be guaranteed 6 to 8 weeks, at a minimum, of parental leave with pay after the infant's birth. In addition, in conformance with federal law, the resident should be allowed to extend the leave time when necessary by using paid vacation time or leave without pay. Coparenting, adopting, or fostering of a child should entitle the resident, regardless of gender, to the same amount of paid leave (6–8 weeks) as a person who takes maternity/paternity leave. Flexibility, creativity, and advanced planning are necessary to arrange schedules that optimize resident education and experience, cultivate equity in sharing workloads, and protect pregnant residents from overly strenuous work experiences at critical times of their pregnancies. (1/13)

PATIENT- AND FAMILY-CENTERED CARE AND THE PEDIATRICIAN'S ROLE

Committee on Hospital Care and Institute for Patient- and Family-Centered Care

ABSTRACT. Drawing on several decades of work with families, pediatricians, other health care professionals, and policy makers, the American Academy of Pediatrics provides a definition of patient- and family-centered care. In pediatrics, patient- and family-centered care is based on the understanding that the family is the child's primary source of strength and support. Further, this approach to care recognizes that the perspectives and information provided by families, children, and young adults are essential components of high-quality clinical decision-making, and that patients and family are integral partners with the health care team. This policy statement outlines the core principles of patient- and family-centered care, summarizes some of the recent literature linking patient- and family-centered care to improved health outcomes, and lists various other benefits to be expected when engaging in patient- and family-centered pediatric practice. The statement concludes with specific recommendations for how pediatricians can integrate patient- and family-centered care in hospitals, clinics, and community settings, and in broader systems of care, as well. (1/12)

PATIENT- AND FAMILY-CENTERED CARE AND THE ROLE OF THE EMERGENCY PHYSICIAN PROVIDING CARE TO A CHILD IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians)

ABSTRACT. Patient- and family-centered care is an approach to health care that recognizes the role of the family in providing medical care; encourages collaboration between the patient, family, and health care professionals; and honors individual and family strengths, cultures, traditions, and expertise. Although there are many opportunities for providing patient- and family-centered care in the emergency department, there are also challenges to doing so. The American Academy of Pediatrics and the American College of Emergency Physicians support promoting patient dignity, comfort, and autonomy; rec-

ognizing the patient and family as key decision-makers in the patient's medical care; recognizing the patient's experience and perspective in a culturally sensitive manner; acknowledging the interdependence of child and parent as well as the pediatric patient's evolving independence; encouraging family-member presence; providing information to the family during interventions; encouraging collaboration with other health care professionals; acknowledging the importance of the patient's medical home; and encouraging institutional policies for patient- and family-centered care. (11/06, reaffirmed 6/09, 10/11)

**PATIENT- AND FAMILY-CENTERED CARE
COORDINATION: A FRAMEWORK FOR INTEGRATING
CARE FOR CHILDREN AND YOUTH ACROSS MULTIPLE
SYSTEMS**

*Council on Children With Disabilities and Medical Home
Implementation Project Advisory Committee*

ABSTRACT. Understanding a care coordination framework, its functions, and its effects on children and families is critical for patients and families themselves, as well as for pediatricians, pediatric medical subspecialists/surgical specialists, and anyone providing services to children and families. Care coordination is an essential element of a transformed American health care delivery system that emphasizes optimal quality and cost outcomes, addresses family-centered care, and calls for partnership across various settings and communities. High-quality, cost-effective health care requires that the delivery system include elements for the provision of services supporting the coordination of care across settings and professionals. This requirement of supporting coordination of care is generally true for health systems providing care for all children and youth but especially for those with special health care needs. At the foundation of an efficient and effective system of care delivery is the patient-/family-centered medical home. From its inception, the medical home has had care coordination as a core element. In general, optimal outcomes for children and youth, especially those with special health care needs, require interfacing among multiple care systems and individuals, including the following: medical, social, and behavioral professionals; the educational system; payers; medical equipment providers; home care agencies; advocacy groups; needed supportive therapies/services; and families. Coordination of care across settings permits an integration of services that is centered on the comprehensive needs of the patient and family, leading to decreased health care costs, reduction in fragmented care, and improvement in the patient/family experience of care. (4/14)

See full text on page 837.

**PATIENT- AND FAMILY-CENTERED CARE OF
CHILDREN IN THE EMERGENCY DEPARTMENT
(TECHNICAL REPORT)**

*Patricia J. O'Malley, MD; Kathleen Brown, MD; Steven
E. Krug, MD; and Committee on Pediatric Emergency
Medicine*

ABSTRACT. Patient- and family-centered care is an innovative approach to the planning, delivery, and evaluation of health care that is grounded in a mutually beneficial partnership among patients, families, and health care

professionals. Providing patient- and family-centered care to children in the emergency department setting presents many opportunities and challenges. This technical report draws on previously published policy statements and reports, reviews the current literature, and describes the present state of practice and research regarding patient- and family-centered care for children in the emergency department setting as well as some of the complexities of providing such care. This technical report has been endorsed by the Academic Pediatric Association (formerly the Ambulatory Pediatric Association), the American College of Osteopathic Emergency Physicians, the National Association of Emergency Medical Technicians, the Institute for Family-Centered Care, and the American College of Emergency Physicians. This report is also supported by the Emergency Nurses Association. (8/08)

**PATIENT SAFETY IN THE PEDIATRIC EMERGENCY
CARE SETTING**

Committee on Pediatric Emergency Medicine

ABSTRACT. Patient safety is a priority for all health care professionals, including those who work in emergency care. Unique aspects of pediatric care may increase the risk of medical error and harm to patients, especially in the emergency care setting. Although errors can happen despite the best human efforts, given the right set of circumstances, health care professionals must work proactively to improve safety in the pediatric emergency care system. Specific recommendations to improve pediatric patient safety in the emergency department are provided in this policy statement. (12/07, reaffirmed 6/11, 7/14)

PAYMENT FOR TELEPHONE CARE

*Section on Telephone Care and Committee on Child Health
Financing*

ABSTRACT. Telephone care in pediatrics requires medical judgment, is associated with practice expense and medical liability risk, and can often substitute for more costly face-to-face care. Despite this, physicians are infrequently paid by patients or third-party payors for medical services provided by telephone. As the costs of maintaining a practice continue to increase, pediatricians are increasingly seeking payment for the time and work involved in telephone care. This statement reviews the role of telephone care in pediatric practice, the current state of payment for telephone care, and the practical issues associated with charging for telephone care services, a service traditionally provided gratis to patients and families. Specific recommendations are presented for appropriate documenting, reporting, and billing for telephone care services. (10/06)

PEDESTRIAN SAFETY

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Each year, approximately 900 pediatric pedestrians younger than 19 years are killed. In addition, 51000 children are injured as pedestrians, and 5300 of them are hospitalized because of their injuries. Parents should be warned that young children often do not have the cognitive, perceptual, and behavioral abilities to negotiate traffic independently. Parents should also be informed about the danger of vehicle back-over injuries to toddlers playing in driveways. Because posttraumatic stress syn-

drome commonly follows even minor pedestrian injury, pediatricians should screen and refer for this condition as necessary. The American Academy of Pediatrics supports community- and school-based strategies that minimize a child's exposure to traffic, especially to high-speed, high-volume traffic. Furthermore, the American Academy of Pediatrics supports governmental and industry action that would lead to improvements in vehicle design, driver manuals, driver education, and data collection for the purpose of reducing pediatric pedestrian injury. (7/09, reaffirmed 8/13)

PEDIATRIC AND ADOLESCENT MENTAL HEALTH EMERGENCIES IN THE EMERGENCY MEDICAL SERVICES SYSTEM (TECHNICAL REPORT)

Margaret A. Dolan, MD; Joel A. Fein, MD, MPH; and Committee on Pediatric Emergency Medicine

ABSTRACT. Emergency department (ED) health care professionals often care for patients with previously diagnosed psychiatric illnesses who are ill, injured, or having a behavioral crisis. In addition, ED personnel encounter children with psychiatric illnesses who may not present to the ED with overt mental health symptoms. Staff education and training regarding identification and management of pediatric mental health illness can help EDs overcome the perceived limitations of the setting that influence timely and comprehensive evaluation. In addition, ED physicians can inform and advocate for policy changes at local, state, and national levels that are needed to ensure comprehensive care of children with mental health illnesses. This report addresses the roles that the ED and ED health care professionals play in emergency mental health care of children and adolescents in the United States, which includes the stabilization and management of patients in mental health crisis, the discovery of mental illnesses and suicidal ideation in ED patients, and approaches to advocating for improved recognition and treatment of mental illnesses in children. The report also addresses special issues related to mental illness in the ED, such as minority populations, children with special health care needs, and children's mental health during and after disasters and trauma. (4/11, reaffirmed 7/14)

PEDIATRIC ANTHRAX CLINICAL MANAGEMENT (CLINICAL REPORT)

John S. Bradley, MD, FAAP, FIDSA, FPIDS; Georgina Peacock, MD, MPH, FAAP; Steven E. Krug, MD, FAAP; William A. Bower, MD, FIDSA; Amanda C. Cohn, MD; Dana Meaney-Delman, MD, MPH, FACOG; Andrew T. Pavia, MD, FAAP, FIDSA; Committee on Infectious Diseases; and Disaster Preparedness Advisory Council

ABSTRACT. Anthrax is a zoonotic disease caused by *Bacillus anthracis*, which has multiple routes of infection in humans, manifesting in different initial presentations of disease. Because *B anthracis* has the potential to be used as a biological weapon and can rapidly progress to systemic anthrax with high mortality in those who are exposed and untreated, clinical guidance that can be quickly implemented must be in place before any intentional release of the agent. This document provides clinical guidance for the prophylaxis and treatment of neonates, infants, children, adolescents, and young adults up to the age of

21 (referred to as "children") in the event of a deliberate *B anthracis* release and offers guidance in areas where the unique characteristics of children dictate a different clinical recommendation from adults. (4/14)

See full text on page 849.

PEDIATRIC ANTHRAX CLINICAL MANAGEMENT: EXECUTIVE SUMMARY (CLINICAL REPORT)

John S. Bradley, MD, FAAP, FIDSA, FPIDS; Georgina Peacock, MD, MPH, FAAP; Steven E. Krug, MD, FAAP; William A. Bower, MD, FIDSA; Amanda C. Cohn, MD; Dana Meaney-Delman, MD, MPH, FACOG; Andrew T. Pavia, MD, FAAP, FIDSA; Committee on Infectious Diseases; and Disaster Preparedness Advisory Council

The use of *Bacillus anthracis* as a biological weapon is considered a potential national security threat by the US government. *B anthracis* has the ability to be used as a biological weapon and to cause anthrax, which can rapidly progress to systemic disease with high mortality in those who are untreated. Therefore, clear plans for managing children after a *B anthracis* bioterror exposure event must be in place before any intentional release of the agent. This document provides a summary of the guidance contained in the clinical report (appendices cited in this executive summary refer to those in the clinical report) for diagnosis and management of anthrax, including antimicrobial treatment and postexposure prophylaxis (PEP), use of antitoxin, and recommendations for use of anthrax vaccine in neonates, infants, children, adolescents, and young adults up to the age of 21 years (referred to as "children"). (4/14)

See full text on page 877.

PEDIATRIC ASPECTS OF INPATIENT HEALTH INFORMATION TECHNOLOGY SYSTEMS (TECHNICAL REPORT)

George R. Kim; Christoph U. Lehmann, MD; and Council on Clinical Information Technology

ABSTRACT. US adoption of health information technology as a path to improved quality of patient care (effectiveness, safety, timeliness, patient-centeredness, efficiency, and equity) has been promoted by the medical community. Children and infants (especially those with special health care needs) are at higher risk than are adults for medical errors and their consequences (particularly in environments in which children are not the primary patient population). However, development and adoption of health information technology tools and practices that promote pediatric quality and patient safety are lagging. Two inpatient clinical processes—medication delivery and patient care transitions—are discussed in terms of health information technology applications that support them and functions that are important to pediatric quality and safety. Pediatricians and their partners (pediatric nurses, pharmacists, etc) must develop awareness of technical and adaptive issues in adopting these tools and collaborate with organizational leaders and developers as advocates for the best interests and safety of pediatric patients. Pediatric health information technology adoption cannot be considered in terms of applications (such as electronic health records or computerized physician order entry) alone but must be considered globally in terms of

technical (health information technology applications), organizational (structures and workflows of care), and cultural (stakeholders) aspects of what is best. (12/08)

PEDIATRIC CARE RECOMMENDATIONS FOR FREESTANDING URGENT CARE FACILITIES

Committee on Pediatric Emergency Medicine

ABSTRACT. Treatment of children at freestanding urgent care facilities has become common in pediatric health care. Well-managed freestanding urgent care facilities can improve the health of the children in their communities, integrate into the medical community, and provide a safe, effective adjunct to, but not a replacement for, the medical home or emergency department. Recommendations are provided for optimizing freestanding urgent care facilities' quality, communication, and collaboration in caring for children. (4/14)

See full text on page 883.

PEDIATRIC FELLOWSHIP TRAINING

Federation of Pediatric Organizations (7/04)

PEDIATRIC MENTAL HEALTH EMERGENCIES IN THE EMERGENCY MEDICAL SERVICES SYSTEM

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians)

ABSTRACT. Emergency departments are vital in the management of pediatric patients with mental health emergencies. Pediatric mental health emergencies are an increasing part of emergency medical practice because emergency departments have become the safety net for a fragmented mental health infrastructure that is experiencing critical shortages in services in all sectors. Emergency departments must safely, humanely, and in a culturally and developmentally appropriate manner manage pediatric patients with undiagnosed and known mental illnesses, including those with mental retardation, autistic spectrum disorders, and attention-deficit/hyperactivity disorder and those experiencing a behavioral crisis. Emergency departments also manage patients with suicidal ideation, depression, escalating aggression, substance abuse, post-traumatic stress disorder, and maltreatment and those exposed to violence and unexpected deaths. Emergency departments must address not only the physical but also the mental health needs of patients during and after mass-casualty incidents and disasters. The American Academy of Pediatrics and the American College of Emergency Physicians support advocacy for increased mental health resources, including improved pediatric mental health tools for the emergency department, increased mental health insurance coverage, and adequate reimbursement at all levels; acknowledgment of the importance of the child's medical home; and promotion of education and research for mental health emergencies. (10/06, reaffirmed 6/09, 4/13)

PEDIATRIC OBSERVATION UNITS (CLINICAL REPORT)

Gregory P. Connors, MD, MPH, MBA; Sanford M. Melzer, MD, MBA; Committee on Hospital Care; and Committee on Pediatric Emergency Medicine

ABSTRACT. Pediatric observation units (OUs) are hospital areas used to provide medical evaluation and/or management for health-related conditions in children,

typically for a well-defined, brief period. Pediatric OUs represent an emerging alternative site of care for selected groups of children who historically may have received their treatment in an ambulatory setting, emergency department, or hospital-based inpatient unit. This clinical report provides an overview of pediatric OUs, including the definitions and operating characteristics of different types of OUs, quality considerations and coding for observation services, and the effect of OUs on inpatient hospital utilization. (6/12)

PEDIATRIC ORGAN DONATION AND TRANSPLANTATION

Committee on Hospital Care, Section on Surgery, and Section on Critical Care

ABSTRACT. Pediatric organ donation and organ transplantation can have a significant life-extending benefit to the young recipients of these organs and a high emotional impact on donor and recipient families. Pediatricians, pediatric medical specialists, and pediatric transplant surgeons need to be better acquainted with evolving national strategies that involve organ procurement and organ transplantation to help acquaint families with the benefits and risks of organ donation and transplantation. Efforts of pediatric professionals are needed to shape public policies to provide a system in which procurement, distribution, and cost are fair and equitable to children and adults. Major issues of concern are availability of and access to donor organs; oversight and control of the process; pediatric medical and surgical consultation and continued care throughout the organ-donation and transplantation process; ethical, social, financial, and follow-up issues; insurance-coverage issues; and public awareness of the need for organ donors of all ages. (3/10, reaffirmed 3/14)

PEDIATRIC PALLIATIVE CARE AND HOSPICE CARE COMMITMENTS, GUIDELINES, AND RECOMMENDATIONS

Section on Hospice and Palliative Medicine and Committee on Hospital Care

ABSTRACT. Pediatric palliative care and pediatric hospice care (PPC-PHC) are often essential aspects of medical care for patients who have life-threatening conditions or need end-of-life care. PPC-PHC aims to relieve suffering, improve quality of life, facilitate informed decision-making, and assist in care coordination between clinicians and across sites of care. Core commitments of PPC-PHC include being patient centered and family engaged; respecting and partnering with patients and families; pursuing care that is high quality, readily accessible, and equitable; providing care across the age spectrum and life span, integrated into the continuum of care; ensuring that all clinicians can provide basic palliative care and consult PPC-PHC specialists in a timely manner; and improving care through research and quality improvement efforts. PPC-PHC guidelines and recommendations include ensuring that all large health care organizations serving children with life-threatening conditions have dedicated interdisciplinary PPC-PHC teams, which should develop collaborative relationships between hospital- and community-based teams; that PPC-PHC be provided as integrated multimodal care and practiced as a cornerstone

of patient safety and quality for patients with life-threatening conditions; that PPC-PHC teams should facilitate clear, compassionate, and forthright discussions about medical issues and the goals of care and support families, siblings, and health care staff; that PPC-PHC be part of all pediatric education and training curricula, be an active area of research and quality improvement, and exemplify the highest ethical standards; and that PPC-PHC services be supported by financial and regulatory arrangements to ensure access to high-quality PPC-PHC by all patients with life-threatening and life-shortening diseases. (10/13)

PEDIATRIC PRIMARY HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. Primary health care is described as accessible and affordable, first contact, continuous and comprehensive, and coordinated to meet the health needs of the individual and the family being served.

Pediatric primary health care encompasses health supervision and anticipatory guidance; monitoring physical and psychosocial growth and development; age-appropriate screening; diagnosis and treatment of acute and chronic disorders; management of serious and life-threatening illness and, when appropriate, referral of more complex conditions; and provision of first contact care as well as coordinated management of health problems requiring multiple professional services.

Pediatric primary health care for children and adolescents is family centered and incorporates community resources and strengths, needs and risk factors, and sociocultural sensitivities into strategies for care delivery and clinical practice. Pediatric primary health care is best delivered within the context of a "medical home," where comprehensive, continuously accessible and affordable care is available and delivered or supervised by qualified child health specialists.

The pediatrician, because of training (which includes 4 years of medical school education, plus an additional 3 or more years of intensive training devoted solely to all aspects of medical care for children and adolescents), coupled with the demonstrated interest in and total professional commitment to the health care of infants, children, adolescents, and young adults, is the most appropriate provider of pediatric primary health care. (1/11, reaffirmed 10/13)

PEDIATRIC SUDDEN CARDIAC ARREST

Section on Cardiology and Cardiac Surgery

ABSTRACT. Pediatric sudden cardiac arrest (SCA), which can cause sudden cardiac death if not treated within minutes, has a profound effect on everyone: children, parents, family members, communities, and health care providers. Preventing the tragedy of pediatric SCA, defined as the abrupt and unexpected loss of heart function, remains a concern to all. The goal of this statement is to increase the knowledge of pediatricians (including primary care providers and specialists) of the incidence of pediatric SCA, the spectrum of causes of pediatric SCA, disease-specific presentations, the role of patient and family screening, the rapidly evolving role of genetic testing, and finally, important aspects of secondary SCA prevention. This statement is not intended to address sudden infant death syndrome

or sudden unexplained death syndrome, nor will specific treatment of individual cardiac conditions be discussed. This statement has been endorsed by the American College of Cardiology, the American Heart Association, and the Heart Rhythm Society. (3/12)

THE PEDIATRICIAN AND CHILDHOOD BEREAVEMENT

Committee on Psychosocial Aspects of Child and

Family Health

ABSTRACT. Pediatricians should understand and evaluate children's reactions to the death of a person important to them by using age-appropriate and culturally sensitive guidance while being alert for normal and complicated grief responses. Pediatricians also should advise and assist families in responding to the child's needs. Sharing, family support, and communication have been associated with positive long-term bereavement adjustment. (2/00, reaffirmed 1/04, 3/13)

THE PEDIATRICIAN AND DISASTER PREPAREDNESS

Committee on Pediatric Emergency Medicine, Committee on

Medical Liability, and Task Force on Terrorism

ABSTRACT. Recent natural disasters and events of terrorism and war have heightened society's recognition of the need for emergency preparedness. In addition to the unique pediatric issues involved in general emergency preparedness, several additional issues related to terrorism preparedness must be considered, including the unique vulnerabilities of children to various agents as well as the limited availability of age- and weight-appropriate antidotes and treatments. Although children may respond more rapidly to therapeutic intervention, they are at the same time more susceptible to various agents and conditions and more likely to deteriorate if not monitored carefully.

The challenge of dealing with the threat of terrorism, natural disasters, and public health emergencies in the United States is daunting not only for disaster planners but also for our medical system and health professionals of all types, including pediatricians. As part of the network of health responders, pediatricians need to be able to answer concerns of patients and families, recognize signs of possible exposure to a weapon of terror, understand first-line response to such attacks, and sufficiently participate in disaster planning to ensure that the unique needs of children are addressed satisfactorily in the overall process. Pediatricians play a central role in disaster and terrorism preparedness with families, children, and their communities. This applies not only to the general pediatrician but also to the pediatric medical subspecialist and pediatric surgical specialist. Families view pediatricians as their expert resource, and most of them expect the pediatrician to be knowledgeable in areas of concern. Providing expert guidance entails educating families in anticipation of events and responding to questions during and after actual events. It is essential that pediatricians educate themselves regarding these issues of emergency preparedness.

For pediatricians, some information is currently available on virtually all of these issues in recently produced printed materials, at special conferences, in broadcasts of various types, and on the Internet. However, selecting

appropriate, accurate sources of information and determining how much information is sufficient remain difficult challenges. Similarly, guidance is needed with respect to developing relevant curricula for medical students and postdoctoral clinical trainees. (2/06, reaffirmed 6/09, 9/13)

THE PEDIATRICIAN WORKFORCE: CURRENT STATUS AND FUTURE PROSPECTS (TECHNICAL REPORT)

David C. Goodman, MD, MS, and Committee on Pediatric Workforce

ABSTRACT. The effective and efficient delivery of children's health care depends on the pediatrician workforce. The number, composition, and distribution of pediatricians necessary to deliver this care have been the subject of long-standing policy and professional debate. This technical report reviews current characteristics and recent trends in the pediatric workforce and couples the workforce to a conceptual model of improvement in children's health and well-being. Important recent changes in the workforce include (1) the growth in the number of pediatricians in relation to the child population, (2) increased numbers of female pediatricians and their attainment of majority gender status in the specialty, (3) the persistence of a large number of international medical graduates entering training programs, (4) a lack of ethnic and racial diversity in pediatricians compared with children, and (5) the persistence of marked regional variation in pediatrician supply. Supply models projecting the pediatric workforce are reviewed and generally indicate that the number of pediatricians per child will increase by 50% over the next 20 years. The differing methods of assessing workforce requirements are presented and critiqued. The report finds that the pediatric workforce is undergoing fundamental changes that will have important effects on the professional lives of pediatricians and children's health care delivery. (7/05)

PEDIATRICIAN WORKFORCE POLICY STATEMENT

Committee on Pediatric Workforce

ABSTRACT. This policy statement reviews important trends and other factors that affect the pediatrician workforce and the provision of pediatric health care, including changes in the pediatric patient population, pediatrician workforce, and nature of pediatric practice. The effect of these changes on pediatricians and the demand for pediatric care are discussed. The American Academy of Pediatrics (AAP) concludes that there is currently a shortage of pediatric medical subspecialists in many fields, as well as a shortage of pediatric surgical specialists. In addition, the AAP believes that the current distribution of primary care pediatricians is inadequate to meet the needs of children living in rural and other underserved areas, and more primary care pediatricians will be needed in the future because of the increasing number of children who have significant chronic health problems, changes in physician work hours, and implementation of current health reform efforts that seek to improve access to comprehensive patient- and family-centered care for all children in a medical home. The AAP is committed to being an active participant in physician workforce policy

development with both professional organizations and governmental bodies to ensure a pediatric perspective on health care workforce issues. The overall purpose of this statement is to summarize policy recommendations and serve as a resource for the AAP and other stakeholders as they address pediatrician workforce issues that ultimately influence the quality of pediatric health care provided to children in the United States. (7/13)

PEDIATRICIAN-FAMILY-PATIENT RELATIONSHIPS: MANAGING THE BOUNDARIES

Committee on Bioethics

ABSTRACT. All professionals are concerned about maintaining the appropriate limits in their relationships with those they serve. Pediatricians should be aware that, under normal circumstances, caring for one's own children presents significant ethical issues. Pediatricians also must strive to maintain appropriate professional boundaries in their relationships with the family members of their patients. Pediatricians should avoid behavior that patients and parents might misunderstand as having sexual or inappropriate social meaning. Romantic and sexual involvement between physicians and patients is unacceptable. The acceptance of gifts or nonmonetary compensation for medical services has the potential to affect the professional relationship adversely. (11/09, reaffirmed 1/14)

THE PEDIATRICIAN'S ROLE IN CHILD MALTREATMENT PREVENTION (CLINICAL REPORT)

Emalee G. Flaherty, MD; John Stirling, Jr, MD; and

Committee on Child Abuse and Neglect

ABSTRACT. It is the pediatrician's role to promote the child's well-being and to help parents raise healthy, well-adjusted children. Pediatricians, therefore, can play an important role in the prevention of child maltreatment. Previous clinical reports and policy statements from the American Academy of Pediatrics have focused on improving the identification and management of child maltreatment. This clinical report outlines how the pediatrician can help to strengthen families and promote safe, stable, nurturing relationships with the aim of preventing maltreatment. After describing some of the triggers and factors that place children at risk for maltreatment, the report describes how pediatricians can identify family strengths, recognize risk factors, provide helpful guidance, and refer families to programs and other resources with the goal of strengthening families, preventing child maltreatment, and enhancing child development. (9/10, reaffirmed 1/14)

THE PEDIATRICIAN'S ROLE IN COMMUNITY PEDIATRICS

Committee on Community Health Services

ABSTRACT. This policy statement reaffirms the pediatrician's role in community pediatrics. It offers pediatricians a definition of community pediatrics and provides a set of specific recommendations that underscore the critical nature of this important dimension of the profession. (4/05, reaffirmed 1/10)

THE PEDIATRICIAN'S ROLE IN DEVELOPMENT AND IMPLEMENTATION OF AN INDIVIDUAL EDUCATION PLAN (IEP) AND/OR AN INDIVIDUAL FAMILY SERVICE PLAN (IFSP)

Committee on Children With Disabilities

ABSTRACT. The Individual Education Plan and Individual Family Service Plan are legally mandated documents developed by a multidisciplinary team assessment that specifies goals and services for each child eligible for special educational services or early intervention services. Pediatricians need to be knowledgeable of federal, state, and local requirements; establish linkages with early intervention, educational professionals, and parent support groups; and collaborate with the team working with individual children. (7/99, reaffirmed 11/02, 1/06)

THE PEDIATRICIAN'S ROLE IN FAMILY SUPPORT AND FAMILY SUPPORT PROGRAMS

Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. Children's social, emotional, and physical health; their developmental trajectory; and the neuro-circuits that are being created and reinforced in their developing brains are all directly influenced by their relationships during early childhood. The stresses associated with contemporary American life can challenge families' abilities to promote successful developmental outcomes and emotional health for their children. Pediatricians are positioned to serve as partners with families and other community providers in supporting the well-being of children and their families. The structure and support of families involve forces that are often outside the agenda of the usual pediatric health supervision visits. Pediatricians must ensure that their medical home efforts promote a holistically healthy family environment for all children. This statement recommends opportunities for pediatricians to develop their expertise in assessing the strengths and stresses in families, in counseling families about strategies and resources, and in collaborating with others in their communities to support family relationships. (11/11)

THE PEDIATRICIAN'S ROLE IN SUPPORTING ADOPTIVE FAMILIES (CLINICAL REPORT)

*Veronnie F. Jones, MD, PhD; Elaine E. Schulte, MD, MPH;
Committee on Early Childhood; and Council on Foster Care, Adoption, and Kinship Care*

ABSTRACT. Each year, more children join families through adoption. Pediatricians have an important role in assisting adoptive families in the various challenges they may face with respect to adoption. The acceptance of the differences between families formed through birth and those formed through adoption is essential in promoting positive emotional growth within the family. It is important for pediatricians to be aware of the adoptive parents' need to be supported in their communication with their adopted children. (9/12)

THE PEDIATRICIAN'S ROLE IN THE EVALUATION AND PREPARATION OF PEDIATRIC PATIENTS UNDERGOING ANESTHESIA

Section on Anesthesiology and Pain Medicine

ABSTRACT. Pediatricians play a key role in helping prepare patients and families for anesthesia and surgery. The questions to be answered by the pediatrician fall into 2 categories. The first involves preparation: is the patient in optimal medical condition for surgery, and are the patient and family emotionally and cognitively ready for surgery? The second category concerns logistics: what communication and organizational needs are necessary to enable safe passage through the perioperative process? This revised statement updates the recommendations for the pediatrician's role in the preoperative preparation of patients. (8/14)

See full text on page 889.

THE PEDIATRICIAN'S ROLE IN THE PREVENTION OF MISSING CHILDREN (CLINICAL REPORT)

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. In 2002, the *Second National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children* report was released by the US Department of Justice, providing new data on a problem that our nation continues to face. This clinical report describes the categories of missing children, the prevalence of each, and prevention strategies that primary care pediatricians can share with parents to increase awareness and education about the safety of their children. (10/04)

PERSONAL WATERCRAFT USE BY CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention

ABSTRACT. The use of personal watercraft (PWC) has increased dramatically during the past decade as have the speed and mobility of the watercraft. A similar dramatic increase in PWC-related injury and death has occurred simultaneously. No one younger than 16 years should operate a PWC. The operator and all passengers must wear US Coast Guard-approved personal flotation devices. Other safety recommendations are suggested for parents and pediatricians. (2/00, reaffirmed 5/04, 1/07, 6/10)

PESTICIDE EXPOSURE IN CHILDREN

Council on Environmental Health

ABSTRACT. This statement presents the position of the American Academy of Pediatrics on pesticides. Pesticides are a collective term for chemicals intended to kill unwanted insects, plants, molds, and rodents. Children encounter pesticides daily and have unique susceptibilities to their potential toxicity. Acute poisoning risks are clear, and understanding of chronic health implications from both acute and chronic exposure are emerging. Epidemiologic evidence demonstrates associations between early life

exposure to pesticides and pediatric cancers, decreased cognitive function, and behavioral problems. Related animal toxicology studies provide supportive biological plausibility for these findings. Recognizing and reducing problematic exposures will require attention to current inadequacies in medical training, public health tracking, and regulatory action on pesticides. Ongoing research describing toxicologic vulnerabilities and exposure factors across the life span are needed to inform regulatory needs and appropriate interventions. Policies that promote integrated pest management, comprehensive pesticide labeling, and marketing practices that incorporate child health considerations will enhance safe use. (11/12)

PESTICIDE EXPOSURE IN CHILDREN (TECHNICAL REPORT)

James R. Roberts, MD, MPH; Catherine J. Karr, MD, PhD;
and Council on Environmental Health

ABSTRACT. Pesticides are a collective term for a wide array of chemicals intended to kill unwanted insects, plants, molds, and rodents. Food, water, and treatment in the home, yard, and school are all potential sources of children's exposure. Exposures to pesticides may be overt or subacute, and effects range from acute to chronic toxicity. In 2008, pesticides were the ninth most common substance reported to poison control centers, and approximately 45% of all reports of pesticide poisoning were for children. Organophosphate and carbamate poisoning are perhaps the most widely known acute poisoning syndromes, can be diagnosed by depressed red blood cell cholinesterase levels, and have available antidotal therapy. However, numerous other pesticides that may cause acute toxicity, such as pyrethroid and neonicotinoid insecticides, herbicides, fungicides, and rodenticides, also have specific toxic effects; recognition of these effects may help identify acute exposures. Evidence is increasingly emerging about chronic health implications from both acute and chronic exposure. A growing body of epidemiological evidence demonstrates associations between parental use of pesticides, particularly insecticides, with acute lymphocytic leukemia and brain tumors. Prenatal, household, and occupational exposures (maternal and paternal) appear to be the largest risks. Prospective cohort studies link early-life exposure to organophosphates and organochlorine pesticides (primarily DDT) with adverse effects on neurodevelopment and behavior. Among the findings associated with increased pesticide levels are poorer mental development by using the Bayley index and increased scores on measures assessing pervasive developmental disorder, inattention, and attention-deficit/hyperactivity disorder. Related animal toxicology studies provide supportive biological plausibility for these findings. Additional data suggest that there may also be an association between parental pesticide use and adverse birth outcomes including physical birth defects, low birth weight, and fetal death, although the data are less robust than for cancer and neurodevelopmental effects.

Children's exposures to pesticides should be limited as much as possible. (11/12)

PHOTOTHERAPY TO PREVENT SEVERE NEONATAL HYPERBILIRUBINEMIA IN THE NEWBORN INFANT 35 OR MORE WEEKS OF GESTATION (TECHNICAL REPORT)

Vinod K. Bhutani, MD, and Committee on Fetus and
Newborn

ABSTRACT. *Objective.* To standardize the use of phototherapy consistent with the American Academy of Pediatrics clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

Methods. Relevant literature was reviewed. Phototherapy devices currently marketed in the United States that incorporate fluorescent, halogen, fiber-optic, or blue light-emitting diode light sources were assessed in the laboratory.

Results. The efficacy of phototherapy units varies widely because of differences in light source and configuration. The following characteristics of a device contribute to its effectiveness: (1) emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum (~460–490 nm); (2) irradiance of at least $30 \mu\text{W}\cdot\text{cm}^{-2}\cdot\text{nm}^{-1}$ (confirmed with an appropriate irradiance meter calibrated over the appropriate wavelength range); (3) illumination of maximal body surface; and (4) demonstration of a decrease in total bilirubin concentrations during the first 4 to 6 hours of exposure.

Recommendations. The intensity and spectral output of phototherapy devices is useful in predicting potential effectiveness in treating hyperbilirubinemia (group B recommendation). Clinical effectiveness should be evaluated before and monitored during use (group B recommendation). Blocking the light source or reducing exposed body surface should be avoided (group B recommendation). Standardization of irradiance meters, improvements in device design, and lower-upper limits of light intensity for phototherapy units merit further study. Comparing the in vivo performance of devices is not practical, in general, and alternative procedures need to be explored. (9/11, reaffirmed 7/14)

PHYSICIAN HEALTH AND WELLNESS (CLINICAL REPORT)

Hilary McClafferty, MD, FAAP; Oscar W. Brown, MD,
FAAP; Section on Integrative Medicine; and Committee on
Practice and Ambulatory Medicine

ABSTRACT. Physician health and wellness is a critical issue gaining national attention because of the high prevalence of physician burnout. Pediatricians and pediatric trainees experience burnout at levels equivalent to other medical specialties, highlighting a need for more effective efforts to promote health and well-being in the pediatric community. This report will provide an overview of physician burnout, an update on work in the field of preventive physician health and wellness, and a discussion of emerging initiatives that have potential to promote health at all levels of pediatric training.

Pediatricians are uniquely positioned to lead this movement nationally, in part because of the emphasis placed on wellness in the Pediatric Milestone Project, a joint collaboration between the Accreditation Council for Graduate Medical Education and the American Board of Pediatrics. Updated core competencies calling for a balanced approach to health, including focus on nutrition, exercise, mindfulness, and effective stress management, signal a paradigm shift and send the message that it is time for pediatricians to cultivate a culture of wellness better aligned with their responsibilities as role models and congruent with advances in pediatric training.

Rather than reviewing programs in place to address substance abuse and other serious conditions in distressed physicians, this article focuses on forward progress in the field, with an emphasis on the need for prevention and anticipation of predictable stressors related to burnout in medical training and practice. Examples of positive progress and several programs designed to promote physician health and wellness are reviewed. Areas where more research is needed are highlighted. (9/14)

See full text on page 899.

PHYSICIAN REFUSAL TO PROVIDE INFORMATION OR TREATMENT ON THE BASIS OF CLAIMS OF CONSCIENCE

Committee on Bioethics

ABSTRACT. Health care professionals may have moral objections to particular medical interventions. They may refuse to provide or cooperate in the provision of these interventions. Such objections are referred to as conscientious objections. Although it may be difficult to characterize or validate claims of conscience, respecting the individual physician's moral integrity is important. Conflicts arise when claims of conscience impede a patient's access to medical information or care. A physician's conscientious objection to certain interventions or treatments may be constrained in some situations. Physicians have a duty to disclose to prospective patients treatments they refuse to perform. As part of informed consent, physicians also have a duty to inform their patients of all relevant and legally available treatment options, including options to which they object. They have a moral obligation to refer patients to other health care professionals who are willing to provide those services when failing to do so would cause harm to the patient, and they have a duty to treat patients in emergencies when referral would significantly increase the probability of mortality or serious morbidity. Conversely, the health care system should make reasonable accommodations for physicians with conscientious objections. (11/09, reaffirmed 1/14)

PHYSICIANS' ROLES IN COORDINATING CARE OF HOSPITALIZED CHILDREN (CLINICAL REPORT)

Patricia S. Lye, MD; Committee on Hospital Care; and Section on Hospital Medicine

ABSTRACT. The care of hospitalized children and adolescents has become increasingly complex and often involves multiple physicians beyond the traditional primary care pediatrician. Hospitalists, medical subspecialists, surgical specialists, and hospital attending physicians may all participate in the care of hospitalized children and youth.

This report summarizes the responsibilities of the pediatrician and other involved physicians in ensuring that children receive coordinated and comprehensive medical care delivered within the context of their medical homes as inpatients, and that care is appropriately continued on an outpatient basis. (9/10)

PLANNED HOME BIRTH

Committee on Fetus and Newborn

ABSTRACT. The American Academy of Pediatrics concurs with the recent statement of the American College of Obstetricians and Gynecologists affirming that hospitals and birthing centers are the safest settings for birth in the United States while respecting the right of women to make a medically informed decision about delivery. This statement is intended to help pediatricians provide supportive, informed counsel to women considering home birth while retaining their role as child advocates and to summarize the standards of care for newborn infants born at home, which are consistent with standards for infants born in a medical care facility. Regardless of the circumstances of his or her birth, including location, every newborn infant deserves health care that adheres to the standards highlighted in this statement, more completely described in other publications from the American Academy of Pediatrics, including *Guidelines for Perinatal Care*. The goal of providing high-quality care to all newborn infants can best be achieved through continuing efforts by all participating health care providers and institutions to develop and sustain communications and understanding on the basis of professional interaction and mutual respect throughout the health care system. (4/13)

POLIOVIRUS

Committee on Infectious Diseases

ABSTRACT. Despite marked progress in global polio eradication, the threat of polio importation into the United States remains; therefore, all children should be protected against the disease. The standard schedule for poliovirus immunization remains 4 doses of inactivated poliovirus vaccine at 2, 4, and 6 through 18 months and 4 through 6 years of age. The minimum interval between doses 1 and 2 and between doses 2 and 3 is 4 weeks, and the minimum interval between doses 3 and 4 is 6 months. The minimum age for dose 1 is 6 weeks. Minimal age and intervals should be used when there is imminent threat of exposure, such as travel to an area in which polio is endemic or epidemic. The final dose in the inactivated poliovirus vaccine series should be administered at 4 through 6 years of age, regardless of the previous number of doses administered before the fourth birthday, and at least 6 months since the last dose was received. (9/11)

POSTDISCHARGE FOLLOW-UP OF INFANTS WITH CONGENITAL DIAPHRAGMATIC HERNIA (CLINICAL REPORT)

Section on Surgery and Committee on Fetus and Newborn

ABSTRACT. Infants with congenital diaphragmatic hernia often require intensive treatment after birth, have prolonged hospitalizations, and have other congenital anomalies. After discharge from the hospital, they may have long-term sequelae such as respiratory insufficiency,

gastroesophageal reflux, poor growth, neurodevelopmental delay, behavior problems, hearing loss, hernia recurrence, and orthopedic deformities. Structured follow-up for these patients facilitates early recognition and treatment of these complications. In this report, follow-up of infants with congenital diaphragmatic hernia is outlined. (3/08, reaffirmed 5/11)

POSTEXPOSURE PROPHYLAXIS IN CHILDREN AND ADOLESCENTS FOR NONOCCUPATIONAL EXPOSURE TO HUMAN IMMUNODEFICIENCY VIRUS (CLINICAL REPORT)

Committee on Pediatric AIDS

ABSTRACT. Exposure to human immunodeficiency virus (HIV) can occur in a number of situations unique to, or more common among, children and adolescents. Guidelines for postexposure prophylaxis (PEP) for occupational and nonoccupational (eg, sexual, needle-sharing) exposures to HIV have been published by the US Public Health Service, but they do not directly address nonoccupational HIV exposures unique to children (such as accidental exposure to human milk from a woman infected with HIV or a puncture wound from a discarded needle on a playground), and they do not provide antiretroviral drug information relevant to PEP in children.

This clinical report reviews issues of potential exposure of children and adolescents to HIV and gives recommendations for PEP in those situations. The risk of HIV transmission from nonoccupational, nonperinatal exposure is generally low. Transmission risk is modified by factors related to the source and extent of exposure. Determination of the HIV infection status of the exposure source may not be possible, and data on transmission risk by exposure type may not exist. Except in the setting of perinatal transmission, no studies have demonstrated the safety and efficacy of postexposure use of antiretroviral drugs for the prevention of HIV transmission in nonoccupational settings. Antiretroviral therapy used for PEP is associated with significant toxicity. The decision to initiate prophylaxis needs to be made in consultation with the patient, the family, and a clinician with experience in treatment of persons with HIV infection. If instituted, therapy should be started as soon as possible after an exposure—no later than 72 hours—and continued for 28 days. Many clinicians would use 3 drugs for PEP regimens, although 2 drugs may be considered in certain circumstances. Instruction for avoiding secondary transmission should be given. Careful follow-up is needed for psychologic support, encouragement of medication adherence, toxicity monitoring, and serial HIV antibody testing. (6/03, reaffirmed 1/07, 10/08)

POSTNATAL CORTICOSTEROIDS TO PREVENT OR TREAT BRONCHOPULMONARY DYSPLASIA

Kristi L. Watterberg, MD, and Committee on Fetus and Newborn

ABSTRACT. The purpose of this revised statement is to review current information on the use of postnatal glucocorticoids to prevent or treat bronchopulmonary dysplasia in the preterm infant and to make updated recommendations regarding their use. High-dose dexamethasone (0.5 mg/kg per day) does not seem to confer

additional therapeutic benefit over lower doses and is not recommended. Evidence is insufficient to make a recommendation regarding other glucocorticoid doses and preparations. The clinician must use clinical judgment when attempting to balance the potential adverse effects of glucocorticoid treatment with those of bronchopulmonary dysplasia. (9/10, reaffirmed 1/14)

POSTNATAL GLUCOSE HOMEOSTASIS IN LATE-PRETERM AND TERM INFANTS (CLINICAL REPORT)

David H. Adamkin, MD, and Committee on Fetus and Newborn

ABSTRACT. This report provides a practical guide and algorithm for the screening and subsequent management of neonatal hypoglycemia. Current evidence does not support a specific concentration of glucose that can discriminate normal from abnormal or can potentially result in acute or chronic irreversible neurologic damage. Early identification of the at-risk infant and institution of prophylactic measures to prevent neonatal hypoglycemia are recommended as a pragmatic approach despite the absence of a consistent definition of hypoglycemia in the literature. (3/11)

PRECERTIFICATION PROCESS

Committee on Hospital Care

ABSTRACT. Precertification is a process still used by health insurance companies to control health care costs. Although we believe precertification is unnecessary and not cost-effective, in those instances where precertification is still being utilized, we suggest that the following procedures be adopted. This statement suggests guidelines that should help achieve this goal while allowing optimal access to care for children. (8/00, reaffirmed 5/05, 11/08)

PREMEDICATION FOR NONEMERGENCY ENDOTRACHEAL INTUBATION IN THE NEONATE (CLINICAL REPORT)

Praveen Kumar, MD; Susan E. Denson, MD; Thomas J. Mancuso, MD; Committee on Fetus and Newborn; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Endotracheal intubation is a common procedure in newborn care. The purpose of this clinical report is to review currently available evidence on use of premedication for intubation, identify gaps in knowledge, and provide guidance for making decisions about the use of premedication. (2/10, reaffirmed 8/13)

PRENATAL SUBSTANCE ABUSE: SHORT- AND LONG-TERM EFFECTS ON THE EXPOSED FETUS (TECHNICAL REPORT)

Marylou Behnke, MD; Vincent C. Smith, MD; Committee on Substance Abuse; and Committee on Fetus and Newborn

ABSTRACT. Prenatal substance abuse continues to be a significant problem in this country and poses important health risks for the developing fetus. The primary care pediatrician's role in addressing prenatal substance exposure includes prevention, identification of exposure, recognition of medical issues for the exposed newborn infant, protection of the infant, and follow-up of the exposed infant. This report will provide information for the most common drugs involved in prenatal exposure: nicotine,

alcohol, marijuana, opiates, cocaine, and methamphetamine. (2/13)

THE PRENATAL VISIT (CLINICAL REPORT)

George J. Cohen, MD, and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. As advocates for children and their families, pediatricians can support and guide expectant parents in the prenatal period. Prenatal visits allow the pediatrician to gather basic information from expectant parents, offer them information and advice, and identify high-risk conditions that may require special care. In addition, a prenatal visit is the first step in establishing a relationship between the family and the pediatrician (the infant's medical home) and in helping the parents develop parenting skills and confidence. There are several possible formats for this first visit. The one used depends on the experience and preference of the parents, the style of the pediatrician's practice, and pragmatic issues of reimbursement. (9/09, reaffirmed 5/14)

PREPARATION FOR EMERGENCIES IN THE OFFICES OF PEDIATRICIANS AND PEDIATRIC PRIMARY CARE PROVIDERS

Committee on Pediatric Emergency Medicine

ABSTRACT. High-quality pediatric emergency care can be provided only through the collaborative efforts of many health care professionals and child advocates working together throughout a continuum of care that extends from prevention and the medical home to prehospital care, to emergency department stabilization, to critical care and rehabilitation, and finally to a return to care in the medical home. At times, the office of the pediatric primary care provider will serve as the entry site into the emergency care system, which comprises out-of-hospital emergency medical services personnel, emergency department nurses and physicians, and other emergency and critical care providers. Recognizing the important role of pediatric primary care providers in the emergency care system for children and understanding the capabilities and limitations of that system are essential if pediatric primary care providers are to offer the best chance at intact survival for every child who is brought to the office with an emergency. Optimizing pediatric primary care provider office readiness for emergencies requires consideration of the unique aspects of each office practice, the types of patients and emergencies that might be seen, the resources on site, and the resources of the larger emergency care system of which the pediatric primary care provider's office is a part. Parent education regarding prevention, recognition, and response to emergencies, patient triage, early recognition and stabilization of pediatric emergencies in the office, and timely transfer to an appropriate facility for definitive care are important responsibilities of every pediatric primary care provider. In addition, pediatric primary care providers can collaborate with out-of-hospital and hospital-based providers and advocate for the best-quality emergency care for their patients. (7/07, reaffirmed 6/11)

PREPARING FOR PEDIATRIC EMERGENCIES: DRUGS TO CONSIDER (CLINICAL REPORT)

Mary A. Hegenbarth, MD, and Committee on Drugs

ABSTRACT. This clinical report provides current recommendations regarding the selection and use of drugs in preparation for pediatric emergencies. It is not intended to be a comprehensive list of all medications that may be used in all emergencies. When possible, dosage recommendations are consistent with those used in current emergency references such as the *Advanced Pediatric Life Support* and *Pediatric Advanced Life Support* textbooks and the recently revised American Heart Association resuscitation guidelines. (2/08, reaffirmed 10/11)

PRESCRIBING ASSISTIVE-TECHNOLOGY SYSTEMS: FOCUS ON CHILDREN WITH IMPAIRED COMMUNICATION (CLINICAL REPORT)

Larry W. Desch, MD; Deborah Gaebler-Spira, MD; and Council on Children With Disabilities

ABSTRACT. This clinical report defines common terms of use and provides information on current practice, research, and limitations of assistive technology that can be used in systems for communication. The assessment process to determine the best devices for use with a particular child (ie, the best fit of a device) is also reviewed. The primary care pediatrician, as part of the medical home, plays an important role in the interdisciplinary effort to provide appropriate assistive technology and may be asked to make a referral for assessment or prescribe a particular device. This report provides resources to assist pediatricians in this role and reviews the interdisciplinary team functional evaluation using standardized assessments; the multiple funding opportunities available for obtaining devices and ways in which pediatricians can assist families with obtaining them; the training necessary to use these systems once the devices are procured; the follow-up evaluation to ensure that the systems are meeting their goals; and the leadership skills needed to advocate for this technology. The American Academy of Pediatrics acknowledges the need for key resources to be identified in the community and recognizes that these resources are a shared medical, educational, therapeutic, and family responsibility. Although this report primarily deals with assistive technology specific for communication impairments, many of the details in this report also can aid in the acquisition and use of other types of assistive technology. (6/08, reaffirmed 1/12)

PRESCRIBING THERAPY SERVICES FOR CHILDREN WITH MOTOR DISABILITIES (CLINICAL REPORT)

Committee on Children With Disabilities

ABSTRACT. Pediatricians often are called on to prescribe physical, occupational, and speech-language therapy services for children with motor disabilities. This report defines the context in which rehabilitation therapies should be prescribed, emphasizing the evaluation and enhancement of the child's function and abilities and participation in age-appropriate life roles. The report encourages pediatricians to work with teams including the parents, child, teachers, therapists, and other physicians to ensure that their patients receive appropriate therapy services. (6/04, reaffirmed 5/07, 5/11)

PRESERVATION OF FERTILITY IN PEDIATRIC AND ADOLESCENT PATIENTS WITH CANCER (TECHNICAL REPORT)

Mary E. Fallat, MD; John Hutter, MD; Committee on Bioethics; Section on Hematology/Oncology; and Section on Surgery

ABSTRACT. Many cancers that present in children and adolescents are curable with surgery, chemotherapy, and/or radiation therapy. Potential adverse consequences of treatment include sterility, infertility, or subfertility as a result of either gonad removal or damage to germ cells from adjuvant therapy. In recent years, treatment of solid tumors and hematologic malignancies has been modified in an attempt to reduce damage to the gonads. Simultaneously, advances in assisted reproductive techniques have led to new possibilities for the prevention and treatment of infertility. This technical report reviews the topic of fertility preservation in pediatric and adolescent patients with cancer, including ethical considerations. (5/08, reaffirmed 2/12)

PREVENTING AND TREATING HOMESICKNESS (CLINICAL REPORT)

Christopher A. Thurber, PhD; Edward Walton, MD; and Council on School Health

ABSTRACT. Homesickness is the distress and functional impairment caused by an actual or anticipated separation from home and attachment objects such as parents. It is characterized by acute longing and preoccupying thoughts of home. Almost all children, adolescents, and adults experience some degree of homesickness when they are apart from familiar people and environments. Pediatricians and other health care professionals are in a unique position to assist families in understanding the etiology, prevention, and treatment of homesickness. In the case of planned separations, such as summer camp, techniques are provided that may aid in prevention. In the case of unanticipated or traumatic separations, such as hospitalization, effective treatment strategies are available. (1/07, reaffirmed 5/12)

PREVENTION AND MANAGEMENT OF PAIN IN THE NEONATE: AN UPDATE

Committee on Fetus and Newborn and Section on Surgery (joint with Canadian Paediatric Society)

ABSTRACT. The prevention of pain in neonates should be the goal of all caregivers, because repeated painful exposures have the potential for deleterious consequences. Neonates at greatest risk of neurodevelopmental impairment as a result of preterm birth (ie, the smallest and sickest) are also those most likely to be exposed to the greatest number of painful stimuli in the NICU. Although there are major gaps in our knowledge regarding the most effective way to prevent and relieve pain in neonates, proven and safe therapies are currently underused for routine minor yet painful procedures. Every health care facility caring for neonates should implement an effective pain-prevention program, which includes strategies for routinely assessing pain, minimizing the number of painful procedures performed, effectively using pharmacologic and nonpharmacologic therapies for the prevention of pain associated with routine minor procedures, and

eliminating pain associated with surgery and other major procedures. (11/06, reaffirmed 5/10)

PREVENTION AND MANAGEMENT OF POSITIONAL SKULL DEFORMITIES IN INFANTS (CLINICAL REPORT)

James Laughlin, MD; Thomas G. Luerksen, MD; Mark S. Dias, MD; Committee on Practice and Ambulatory Medicine; and Section on Neurological Surgery

ABSTRACT. Positional skull deformities may be present at birth or may develop during the first few months of life. Since the early 1990s, US pediatricians have seen an increase in the number of children with cranial asymmetry, particularly unilateral flattening of the occiput, likely attributable to parents following the American Academy of Pediatrics "Back to Sleep" positioning recommendations aimed at decreasing the risk of sudden infant death syndrome. Positional skull deformities are generally benign, reversible head-shape anomalies that do not require surgical intervention, as opposed to craniosynostosis, which can result in neurologic damage and progressive craniofacial distortion. Although associated with some risk of positional skull deformity, healthy young infants should be placed down for sleep on their backs. The practice of putting infants to sleep on their backs has been associated with a drastic decrease in the incidence of sudden infant death syndrome. Pediatricians need to be able to properly differentiate infants with benign skull deformities from those with craniosynostosis, educate parents on methods of proactively decreasing the likelihood of the development of occipital flattening, initiate appropriate management, and make referrals when necessary. This report provides guidance for the prevention, diagnosis, and management of positional skull deformity in an otherwise normal infant without evidence of associated anomalies, syndromes, or spinal disease. (11/11)

PREVENTION AND TREATMENT OF TYPE 2 DIABETES MELLITUS IN CHILDREN, WITH SPECIAL EMPHASIS ON AMERICAN INDIAN AND ALASKA NATIVE CHILDREN (CLINICAL REPORT)

Committee on Native American Child Health and Section on Endocrinology

ABSTRACT. The emergence of type 2 diabetes mellitus in the American Indian/Alaska Native pediatric population presents a new challenge for pediatricians and other health care professionals. This chronic disease requires preventive efforts, early diagnosis, and collaborative care of the patient and family within the context of a medical home. (10/03, reaffirmed 10/08)

PREVENTION OF AGRICULTURAL INJURIES AMONG CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention and Committee on Community Health Services

ABSTRACT. Although the annual number of farm deaths to children and adolescents has decreased since publication of the 1988 American Academy of Pediatrics statement, "Rural Injuries," the rate of nonfatal farm injuries has increased. Approximately 100 unintentional injury deaths occur annually to children and adolescents on US farms, and an additional 22 000 injuries to children younger than 20 years occur on farms. Relatively

few adolescents are employed on farms compared with other types of industry, yet the proportion of fatalities in agriculture is higher than that for any other type of adolescent employment. The high mortality and severe morbidity associated with farm injuries require continuing and improved injury-control strategies. This statement provides recommendations for pediatricians regarding patient and community education as well as public advocacy related to agricultural injury prevention in childhood and adolescence. (10/01, reaffirmed 1/07, 11/11)

PREVENTION OF CHOKING AMONG CHILDREN

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Choking is a leading cause of morbidity and mortality among children, especially those aged 3 years or younger. Food, coins, and toys are the primary causes of choking-related injury and death. Certain characteristics, including shape, size, and consistency, of certain toys and foods increase their potential to cause choking among children. Childhood choking hazards should be addressed through comprehensive and coordinated prevention activities. The US Consumer Product Safety Commission (CPSC) should increase efforts to ensure that toys that are sold in retail store bins, vending machines, or on the Internet have appropriate choking-hazard warnings; work with manufacturers to improve the effectiveness of recalls of products that pose a choking risk to children; and increase efforts to prevent the resale of these recalled products via online auction sites. Current gaps in choking-prevention standards for children's toys should be reevaluated and addressed, as appropriate, via revisions to the standards established under the Child Safety Protection Act, the Consumer Product Safety Improvement Act, or regulation by the CPSC. Prevention of food-related choking among children in the United States has been inadequately addressed at the federal level. The US Food and Drug Administration should establish a systematic, institutionalized process for examining and addressing the hazards of food-related choking. This process should include the establishment of the necessary surveillance, hazard evaluation, enforcement, and public education activities to prevent food-related choking among children. While maintaining its highly cooperative arrangements with the CPSC and the US Department of Agriculture, the Food and Drug Administration should have the authority to address choking-related risks of all food products, including meat products that fall under the jurisdiction of the US Department of Agriculture. The existing National Electronic Injury Surveillance System–All Injury Program of the CPSC should be modified to conduct more-detailed surveillance of choking on food among children. Food manufacturers should design new foods and redesign existing foods to avoid shapes, sizes, textures, and other characteristics that increase choking risk to children, to the extent possible. Pediatricians, dentists, and other infant and child health care providers should provide choking-prevention counseling to parents as an integral part of anticipatory guidance activities. (2/10)

PREVENTION OF DROWNING

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Drowning is a leading cause of injury-related death in children. In 2006, fatal drowning claimed the lives of approximately 1100 US children younger than 20 years. A number of strategies are available to prevent these tragedies. As educators and advocates, pediatricians can play an important role in the prevention of drowning. (5/10)

PREVENTION OF DROWNING (TECHNICAL REPORT)

Committee on Injury, Violence, and Poison Prevention and

Jeffrey Weiss, MD

ABSTRACT. Drowning is a leading cause of injury-related death in children. In 2006, approximately 1100 US children younger than 20 years died from drowning. A number of strategies are available to prevent these tragedies. As educators and advocates, pediatricians can play an important role in the prevention of drowning. (5/10)

PREVENTION OF PEDIATRIC OVERWEIGHT AND OBESITY

Committee on Nutrition

ABSTRACT. The dramatic increase in the prevalence of childhood overweight and its resultant comorbidities are associated with significant health and financial burdens, warranting strong and comprehensive prevention efforts. This statement proposes strategies for early identification of excessive weight gain by using body mass index, for dietary and physical activity interventions during health supervision encounters, and for advocacy and research. (8/03, reaffirmed 10/06)

PREVENTION OF ROTAVIRUS DISEASE: UPDATED GUIDELINES FOR USE OF ROTAVIRUS VACCINE

Committee on Infectious Diseases

ABSTRACT. This statement updates and replaces the 2007 American Academy of Pediatrics statement for prevention of rotavirus gastroenteritis. In February 2006, a live oral human-bovine reassortant rotavirus vaccine (RV5 [RotaTeq]) was licensed as a 3-dose series for use in infants in the United States. The American Academy of Pediatrics recommended routine use of RV5 in infants in the United States. In April 2008, a live, oral, human attenuated rotavirus vaccine (RV1 [Rotarix]) was licensed as a 2-dose series for use in infants in the United States. The American Academy of Pediatrics recommends routine immunization of infants in the United States with rotavirus vaccine. The American Academy of Pediatrics does not express a preference for either RV5 or RV1. RV5 is to be administered orally in a 3-dose series with doses administered at 2, 4, and 6 months of age; RV1 is to be administered orally in a 2-dose series with doses administered at 2 and 4 months of age. The first dose of rotavirus vaccine should be administered from 6 weeks through 14 weeks, 6 days of age. The minimum interval between doses of rotavirus vaccine is 4 weeks. All doses should be administered by 8 months, 0 days of age. Recommendations in this statement also address the maximum ages for doses, contraindications, precautions, and special situations for administration of rotavirus vaccine. (3/09)

PREVENTION OF SEXUAL HARASSMENT IN THE WORKPLACE AND EDUCATIONAL SETTINGS

Committee on Pediatric Workforce

ABSTRACT. The American Academy of Pediatrics is committed to working to ensure that workplaces and educational settings in which pediatricians spend time are free of sexual harassment. The purpose of this statement is to heighten awareness and sensitivity to this important issue, recognizing that institutions, clinics, and office-based practices may have existing policies. (10/06, reaffirmed 5/09, 1/12)

THE PREVENTION OF UNINTENTIONAL INJURY AMONG AMERICAN INDIAN AND ALASKA NATIVE CHILDREN: A SUBJECT REVIEW (CLINICAL REPORT)

Committee on Native American Child Health and Committee on Injury and Poison Prevention

ABSTRACT. Among ethnic groups in the United States, American Indian and Alaska Native (AI/AN) children experience the highest rates of injury mortality and morbidity. Injury mortality rates for AI/AN children have decreased during the past quarter century, but remain almost double the rate for all children in the United States. The Indian Health Service (IHS), the federal agency with the primary responsibility for the health care of AI/AN people, has sponsored an internationally recognized injury prevention program designed to reduce the risk of injury death by addressing community-specific risk factors. Model programs developed by the IHS and tribal governments have led to successful outcomes in motor vehicle occupant safety, drowning prevention, and fire safety. Injury prevention programs in tribal communities require special attention to the sovereignty of tribal governments and the unique cultural aspects of health care and communication. Pediatricians working with AI/AN children on reservations or in urban environments are strongly urged to collaborate with tribes and the IHS to create community-based coalitions and develop programs to address highly preventable injury-related mortality and morbidity. Strong advocacy also is needed to promote childhood injury prevention as an important priority for federal agencies and tribes. (12/99, reaffirmed 12/02 COIVPP, 5/03 CONACH, 1/06, 1/09)

PREVENTION OF VARICELLA: UPDATE OF RECOMMENDATIONS FOR USE OF QUADRIVALENT AND MONOVALENT VARICELLA VACCINES IN CHILDREN

Committee on Infectious Diseases

ABSTRACT. Two varicella-containing vaccines are licensed for use in the United States: monovalent varicella vaccine (Varivax [Merck & Co, Inc, West Point, PA]) and quadrivalent measles-mumps-rubella-varicella vaccine (MMRV) (ProQuad [Merck & Co, Inc]). It is estimated from postlicensure data that after vaccination at 12 through 23 months of age, 7 to 9 febrile seizures occur per 10 000 children who receive the MMRV, and 3 to 4 febrile seizures occur per 10 000 children who receive the measles-mumps-rubella (MMR) and varicella vaccines administered concurrently but at separate sites. Thus, 1 additional febrile seizure is expected to occur per approximately 2300 to 2600 children 12 to 23 months old vaccinated with the MMRV, when compared with separate MMR and varicella vaccine administration. The period

of risk for febrile seizures is from 5 through 12 days after receipt of the vaccine(s). No increased risk of febrile seizures is seen among patients 4 to 6 years of age receiving MMRV. Febrile seizures do not predispose to epilepsy or neurodevelopmental delays later in life and are not associated with long-term health impairment. The American Academy of Pediatrics recommends that either MMR and varicella vaccines separately or the MMRV be used for the first dose of measles, mumps, rubella, and varicella vaccines administered at 12 through 47 months of age. For the first dose of measles, mumps, rubella, and varicella vaccines administered at ages 48 months and older, and for dose 2 at any age (15 months to 12 years), use of MMRV generally is preferred over separate injections of MMR and varicella vaccines. (8/11)

PREVENTIVE ORAL HEALTH INTERVENTION FOR PEDIATRICIANS

Section on Pediatric Dentistry and Oral Health

ABSTRACT. This policy is a compilation of current concepts and scientific evidence required to understand and implement practice-based preventive oral health programs designed to improve oral health outcomes for all children and especially children at significant risk of dental decay. In addition, it reviews cariology and caries risk assessment and defines, through available evidence, appropriate recommendations for preventive oral health intervention by primary care pediatric practitioners. (12/08)

PRINCIPLES FOR THE DEVELOPMENT AND USE OF QUALITY MEASURES

Steering Committee on Quality Improvement and Management and Committee on Practice and Ambulatory Medicine

ABSTRACT. The American Academy of Pediatrics and its members are committed to improving the health care system to provide the highest-quality and safest health care for infants, children, adolescents, and young adults. This statement is intended as a guide for pediatricians and pediatric leadership on the appropriate uses of quality measures and the criteria on which they should be based. The statement summarizes the current national efforts on quality measurement and provides a set of principles for the development, use, and evaluation of quality measures for improving children's health and health care. The American Academy of Pediatrics recommends that these measures address important issues for children; be appropriate for children's health and health care, scientifically valid, and feasible; and focus on what can be improved. In addition, the American Academy of Pediatrics supports reasonable principles for the oversight and implementation of pay-for-performance programs. (2/08)

PRINCIPLES OF HEALTH CARE FINANCING

Committee on Child Health Financing

ABSTRACT. The American Academy of Pediatrics advocates that all children must have health insurance coverage that ensures them access to affordable and comprehensive quality care. Access to care depends on the design and implementation of payment systems that ensure the economic viability of the medical home; support and grow the professional pediatric workforce; promote the adoption

and implementation of health information technology; enhance medical education, training, and research; and encourage and reward quality-improvement programs that advance and strengthen the medical home. Health insurance plans must be portable from state to state, with administrative procedures to eliminate breaks and gaps in coverage to ensure continuous coverage from year to year. Plans should ensure free choice of clinicians and foster coordination with public and private community-based programs for infants, children, and adolescents through the age of 26. The scope of services provided by all health plans must include preventive, acute and chronic illness, behavioral, inpatient, emergency, and home health care. These plans must be affordable and have cost-sharing policies that protect patients and families from financial strain and are without risk of loss of benefits because of plan design, current illness, or preexisting condition. (10/10, reaffirmed 4/13)

PRINCIPLES OF JUDICIOUS ANTIBIOTIC PRESCRIBING FOR UPPER RESPIRATORY TRACT INFECTIONS IN PEDIATRICS (CLINICAL REPORT)

Committee on Infectious Diseases

ABSTRACT. Most upper respiratory tract infections are caused by viruses and require no antibiotics. This clinical report focuses on antibiotic prescribing strategies for bacterial upper respiratory tract infections, including acute otitis media, acute bacterial sinusitis, and streptococcal pharyngitis. The principles for judicious antibiotic prescribing that are outlined focus on applying stringent diagnostic criteria, weighing the benefits and harms of antibiotic therapy, and understanding situations when antibiotics may not be indicated. The principles can be used to amplify messages from recent clinical guidelines for local guideline development and for patient communication; they are broadly applicable to antibiotic prescribing in general. (11/13)

PRINCIPLES OF PEDIATRIC PATIENT SAFETY: REDUCING HARM DUE TO MEDICAL CARE

Steering Committee on Quality Improvement and Management and Committee on Hospital Care

ABSTRACT. Pediatricians are rendering care in an environment that is increasingly complex, which results in multiple opportunities to cause unintended harm. National awareness of patient safety risks has grown in the 10 years since the Institute of Medicine published its report *To Err Is Human*, and patients and society as a whole continue to challenge health care providers to examine their practices and implement safety solutions. The depth and breadth of harm incurred by the practice of medicine is still being defined as reports continue to uncover a variety of avoidable errors, from those that involve specific high-risk medications to those that are more generalizable, such as patient misidentification. Pediatricians in all venues must have a working knowledge of patient-safety language, advocate for best practices that attend to risks that are unique to children, identify and support a culture of safety, and lead efforts to eliminate avoidable harm in any setting in which medical care is rendered to children. (5/11)

PROBIOTICS AND PREBIOTICS IN PEDIATRICS (CLINICAL REPORT)

Dan W. Thomas, MD; Frank R. Greer, MD; Committee on Nutrition; and Section on Gastroenterology, Hepatology, and Nutrition

ABSTRACT. This clinical report reviews the currently known health benefits of probiotic and prebiotic products, including those added to commercially available infant formula and other food products for use in children. Probiotics are supplements or foods that contain viable microorganisms that cause alterations of the microflora of the host. Use of probiotics has been shown to be modestly effective in randomized clinical trials (RCTs) in (1) treating acute viral gastroenteritis in healthy children; and (2) preventing antibiotic-associated diarrhea in healthy children. There is some evidence that probiotics prevent necrotizing enterocolitis in very low birth weight infants (birth weight between 1000 and 1500 g), but more studies are needed. The results of RCTs in which probiotics were used to treat childhood *Helicobacter pylori* gastritis, irritable bowel syndrome, chronic ulcerative colitis, and infantile colic, as well as in preventing childhood atopy, although encouraging, are preliminary and require further confirmation. Probiotics have not been proven to be beneficial in treating or preventing human cancers or in treating children with Crohn disease. There are also safety concerns with the use of probiotics in infants and children who are immunocompromised, chronically debilitated, or seriously ill with indwelling medical devices.

Prebiotics are supplements or foods that contain a non-digestible food ingredient that selectively stimulates the favorable growth and/or activity of indigenous probiotic bacteria. Human milk contains substantial quantities of prebiotics. There is a paucity of RCTs examining prebiotics in children, although there may be some long-term benefit of prebiotics for the prevention of atopic eczema and common infections in healthy infants. Confirmatory well-designed clinical research studies are necessary. (11/10)

PROFESSIONAL LIABILITY INSURANCE AND MEDICOLEGAL EDUCATION FOR PEDIATRIC RESIDENTS AND FELLOWS

Committee on Medical Liability and Risk Management

ABSTRACT. The American Academy of Pediatrics believes that pediatric residents and fellows should be fully informed of the scope and limitations of their professional liability insurance coverage while in training. The academy states that residents and fellows should be educated by their training institutions on matters relating to medical liability and the importance of maintaining adequate and continuous professional liability insurance coverage throughout their careers in medicine. (8/11)

PROFESSIONALISM IN PEDIATRICS: STATEMENT OF PRINCIPLES

Committee on Bioethics

ABSTRACT. The purpose of this statement is to delineate the concept of professionalism within the context of pediatrics and to provide a brief statement of principles to guide the behavior and professional practice of pediatricians. (10/07, reaffirmed 5/11)

PROFESSIONALISM IN PEDIATRICS (TECHNICAL REPORT)

Mary E. Fallat, MD; Jacqueline Glover, PhD; and Committee on Bioethics

ABSTRACT. The purpose of this report is to provide a concrete overview of the ideal standards of behavior and professional practice to which pediatricians should aspire and by which students and residents can be evaluated. Recognizing that the ideal is not always achievable in the practical sense, this document details the key components of professionalism in pediatric practice with an emphasis on core professional values for which pediatricians should strive and that will serve as a moral compass needed to provide quality care for children and their families. (10/07, reaffirmed 5/11)

PROMOTING EDUCATION, MENTORSHIP, AND SUPPORT FOR PEDIATRIC RESEARCH

Committee on Pediatric Research

ABSTRACT. Pediatricians play a key role in advancing child health research to best attain and improve the physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. Child health presents unique issues that require investigators who specialize in pediatric research. In addition, the scope of the pediatric research enterprise is transdisciplinary and includes the full spectrum of basic science, translational, community-based, health services, and child health policy research. Although most pediatricians do not directly engage in research, knowledge of research methodologies and approaches promotes critical evaluation of scientific literature, the practice of evidence-based medicine, and advocacy for evidence-based child health policy. This statement includes specific recommendations to promote further research education and support at all levels of pediatric training, from premedical to continuing medical education, as well as recommendations to increase support and mentorship for research activities. Pediatric research is crucial to the American Academy of Pediatrics' goal of improving the health of all children. The American Academy of Pediatrics continues to promote and encourage efforts to facilitate the creation of new knowledge and ways to reduce barriers experienced by trainees, practitioners, and academic faculty pursuing research. (4/14)

See full text on page 907.

PROMOTING THE PARTICIPATION OF CHILDREN WITH DISABILITIES IN SPORTS, RECREATION, AND PHYSICAL ACTIVITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Paul S. Carbone, MD; and Council on Children With Disabilities

ABSTRACT. The benefits of physical activity are universal for all children, including those with disabilities. The participation of children with disabilities in sports and recreational activities promotes inclusion, minimizes deconditioning, optimizes physical functioning, and enhances overall well-being. Despite these benefits, children with disabilities are more restricted in their participation, have lower levels of fitness, and have higher levels of obesity than their peers without disabilities. Pediatricians and parents may overestimate the risks or overlook the benefits of physical activity in children with disabilities. Well-informed decisions regarding each child's partici-

pation must consider overall health status, individual activity preferences, safety precautions, and availability of appropriate programs and equipment. Health supervision visits afford pediatricians, children with disabilities, and parents opportunities to collaboratively generate goal-directed activity "prescriptions." Child, family, financial, and societal barriers to participation need to be directly identified and addressed in the context of local, state, and federal laws. The goal is inclusion for all children with disabilities in appropriate activities. This clinical report discusses the importance of physical activity, recreation, and sports participation for children with disabilities and offers practical suggestions to pediatric health care professionals for the promotion of participation. (5/08, reaffirmed 1/12)

PROMOTING THE WELL-BEING OF CHILDREN WHOSE PARENTS ARE GAY OR LESBIAN

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. To promote optimal health and well-being of all children, the American Academy of Pediatrics (AAP) supports access for all children to (1) civil marriage rights for their parents and (2) willing and capable foster and adoptive parents, regardless of the parents' sexual orientation. The AAP has always been an advocate for, and has developed policies to support, the optimal physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. In so doing, the AAP has supported families in all their diversity, because the family has always been the basic social unit in which children develop the supporting and nurturing relationships with adults that they need to thrive. Children may be born to, adopted by, or cared for temporarily by married couples, nonmarried couples, single parents, grandparents, or legal guardians, and any of these may be heterosexual, gay or lesbian, or of another orientation. Children need secure and enduring relationships with committed and nurturing adults to enhance their life experiences for optimal social-emotional and cognitive development. Scientific evidence affirms that children have similar developmental and emotional needs and receive similar parenting whether they are raised by parents of the same or different genders. If a child has 2 living and capable parents who choose to create a permanent bond by way of civil marriage, it is in the best interests of their child(ren) that legal and social institutions allow and support them to do so, irrespective of their sexual orientation. If 2 parents are not available to the child, adoption or foster parenting remain acceptable options to provide a loving home for a child and should be available without regard to the sexual orientation of the parent(s). (3/13)

PROMOTING THE WELL-BEING OF CHILDREN WHOSE PARENTS ARE GAY OR LESBIAN (TECHNICAL REPORT)

Ellen C. Perrin, MD, MA; Benjamin S. Siegel, MD; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Extensive data available from more than 30 years of research reveal that children raised by gay and lesbian parents have demonstrated resilience with regard to social, psychological, and sexual health despite economic

and legal disparities and social stigma. Many studies have demonstrated that children's well-being is affected much more by their relationships with their parents, their parents' sense of competence and security, and the presence of social and economic support for the family than by the gender or the sexual orientation of their parents. Lack of opportunity for same-gender couples to marry adds to families' stress, which affects the health and welfare of all household members. Because marriage strengthens families and, in so doing, benefits children's development, children should not be deprived of the opportunity for their parents to be married. Paths to parenthood that include assisted reproductive techniques, adoption, and foster parenting should focus on competency of the parents rather than their sexual orientation. (3/13)

PROMOTION OF HEALTHY WEIGHT-CONTROL PRACTICES IN YOUNG ATHLETES

Committee on Sports Medicine and Fitness

ABSTRACT. Children and adolescents are often involved in sports in which weight loss or weight gain is perceived as an advantage. This policy statement describes unhealthy weight-control practices that may be harmful to the health and/or performance of athletes. Healthy methods of weight loss and weight gain are discussed, and physicians are given resources and recommendations that can be used to counsel athletes, parents, coaches, and school administrators in discouraging inappropriate weight-control behaviors and encouraging healthy methods of weight gain or loss, when needed. (12/05)

PROTECTING CHILDREN FROM SEXUAL ABUSE BY HEALTH CARE PROVIDERS

Committee on Child Abuse and Neglect

ABSTRACT. Sexual abuse or exploitation of children is never acceptable. Such behavior by health care providers is particularly concerning because of the trust that children and their families place on adults in the health care profession. The American Academy of Pediatrics strongly endorses the social and moral prohibition against sexual abuse or exploitation of children by health care providers. The academy opposes any such sexual abuse or exploitation by providers, particularly by the academy's members. Health care providers should be trained to recognize and abide by appropriate provider-patient boundaries. Medical institutions should screen staff members for a history of child abuse issues, train them to respect and maintain appropriate boundaries, and establish policies and procedures to receive and investigate concerns about patient abuse. Each person has a responsibility to ensure the safety of children in health care settings and to scrupulously follow appropriate legal and ethical reporting and investigation procedures. (6/11)

PROTECTIVE EYEWEAR FOR YOUNG ATHLETES

Committee on Sports Medicine and Fitness (joint with American Academy of Ophthalmology)

ABSTRACT. The American Academy of Pediatrics and American Academy of Ophthalmology strongly recommend protective eyewear for all participants in sports in which there is risk of eye injury. Protective eyewear should be mandatory for athletes who are functionally

1-eyed and for athletes whose ophthalmologists recommend eye protection after eye surgery or trauma. (3/04, reaffirmed 2/08, 6/11)

PROVIDING A PRIMARY CARE MEDICAL HOME FOR CHILDREN AND YOUTH WITH CEREBRAL PALSY (CLINICAL REPORT)

Gregory S. Liptak, MD, MPH; Nancy A. Murphy, MD; and Council on Children With Disabilities

ABSTRACT. All primary care providers will care for children with cerebral palsy in their practice. In addition to well-child and acute illness care, the role of the medical home in the management of these children includes diagnosis, planning for interventions, authorizing treatments, and follow-up. Optimizing health and well-being for children with cerebral palsy and their families entails family-centered care provided in the medical home; comanagement is the most common model. This report reviews the aspects of care specific to cerebral palsy that a medical home should provide beyond the routine health care needed by all children. (10/11)

PROVIDING A PRIMARY CARE MEDICAL HOME FOR CHILDREN AND YOUTH WITH SPINA BIFIDA (CLINICAL REPORT)

Robert Burke, MD, MPH; Gregory S. Liptak, MD, MPH; and Council on Children With Disabilities

ABSTRACT. The pediatric primary care provider in the medical home has a central and unique role in the care of children with spina bifida. The primary care provider addresses not only the typical issues of preventive and acute health care but also the needs specific to these children. Optimal care requires communication and comanagement with pediatric medical and developmental subspecialists, surgical specialists, therapists, and community providers. The medical home provider is essential in supporting the family and advocating for the child from the time of entry into the practice through adolescence, which includes transition and transfer to adult health care. This report reviews aspects of care specific to the infant with spina bifida (particularly myelomeningocele) that will facilitate optimal medical, functional, and developmental outcomes. (11/11)

PROVIDING CARE FOR CHILDREN AND ADOLESCENTS FACING HOMELESSNESS AND HOUSING INSECURITY

Council on Community Pediatrics

ABSTRACT. Child health and housing security are closely intertwined, and children without homes are more likely to suffer from chronic disease, hunger, and malnutrition than are children with homes. Homeless children and youth often have significant psychosocial development issues, and their education is frequently interrupted. Given the overall effects that homelessness can have on a child's health and potential, it is important for pediatricians to recognize the factors that lead to homelessness, understand the ways that homelessness and its causes can lead to poor health outcomes, and when possible, help children and families mitigate some of the effects of homelessness. Through practice change, partnership with community resources, awareness, and advocacy, pediatricians

can help optimize the health and well-being of children affected by homelessness. (5/13)

PROVIDING CARE FOR IMMIGRANT, MIGRANT, AND BORDER CHILDREN

Council on Community Pediatrics

ABSTRACT. This policy statement, which recognizes the large changes in immigrant status since publication of the 2005 statement "Providing Care for Immigrant, Homeless, and Migrant Children," focuses on strategies to support the health of immigrant children, infants, adolescents, and young adults. Homeless children will be addressed in a forthcoming separate statement ("Providing Care for Children and Adolescents Facing Homelessness and Housing Insecurity"). While recognizing the diversity across and within immigrant, migrant, and border populations, this statement provides a basic framework for serving and advocating for all immigrant children, with a particular focus on low-income and vulnerable populations. Recommendations include actions needed within and outside the health care system, including expansion of access to high-quality medical homes with culturally and linguistically effective care as well as education and literacy programs. The statement recognizes the unique and special role that pediatricians can play in the lives of immigrant children and families. Recommendations for policies that support immigrant child health are included. (5/13)

PROVISION OF EDUCATIONALLY RELATED SERVICES FOR CHILDREN AND ADOLESCENTS WITH CHRONIC DISEASES AND DISABLING CONDITIONS

Council on Children With Disabilities

ABSTRACT. Children and adolescents with chronic diseases and disabling conditions often need educationally related services. As medical home providers, physicians and other health care professionals can assist children, adolescents, and their families with the complex federal, state, and local laws, regulations, and systems associated with these services. Expanded roles for physicians and other health care professionals in individualized family service plan, individualized education plan, and Section 504 plan development and implementation are recommended. Recent updates to the Individuals With Disabilities Education Act will also affect these services. Funding for these services by private and nonprivate sources also continue to affect the availability of these educationally related services.

The complex range of federal, state, and local laws, regulations, and systems for special education and related services for children and adolescents in public schools is beyond the scope of this statement. Readers are referred to the American Academy of Pediatrics policy statement "The Pediatrician's Role in Development and Implementation of an Individual Education Plan (IEP) and/or an Individual Family Service Plan (IFSP)" for additional background materials. The focus of this statement is the role that health care professionals have in determining and managing educationally related services in the school setting.

This policy statement is a revision of a previous statement, "Provision of Educationally Related Services for

Children and Adolescents With Chronic Diseases and Disabling Conditions," published in February 2000 by the Committee on Children With Disabilities (<http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/2/448>). (6/07)

PSYCHOLOGICAL MALTREATMENT (CLINICAL REPORT)

Roberta Hibbard, MD; Jane Barlow, Dphil; Harriet

MacMillan, MD; Committee on Child Abuse and Neglect (joint with American Academy of Child and Adolescent Psychiatry Child Maltreatment and Violence Committee)

ABSTRACT. Psychological or emotional maltreatment of children may be the most challenging and prevalent form of child abuse and neglect. Caregiver behaviors include acts of omission (ignoring need for social interactions) or commission (spurning, terrorizing); may be verbal or nonverbal, active or passive, and with or without intent to harm; and negatively affect the child's cognitive, social, emotional, and/or physical development. Psychological maltreatment has been linked with disorders of attachment, developmental and educational problems, socialization problems, disruptive behavior, and later psychopathology. Although no evidence-based interventions that can prevent psychological maltreatment have been identified to date, it is possible that interventions shown to be effective in reducing overall types of child maltreatment, such as the Nurse Family Partnership, may have a role to play. Furthermore, prevention before occurrence will require both the use of universal interventions aimed at promoting the type of parenting that is now recognized to be necessary for optimal child development, alongside the use of targeted interventions directed at improving parental sensitivity to a child's cues during infancy and later parent-child interactions. Intervention should, first and foremost, focus on a thorough assessment and ensuring the child's safety. Potentially effective treatments include cognitive behavioral parenting programs and other psychotherapeutic interventions. The high prevalence of psychological abuse in advanced Western societies, along with the serious consequences, point to the importance of effective management. Pediatricians should be alert to the occurrence of psychological maltreatment and identify ways to support families who have risk indicators for, or evidence of, this problem. (7/12)

PSYCHOSOCIAL IMPLICATIONS OF DISASTER OR TERRORISM ON CHILDREN: A GUIDE FOR THE PEDIATRICIAN (CLINICAL REPORT)

Joseph F. Hagan, Jr, MD, Committee on Psychosocial Aspects of Child and Family Health, and Task Force on Terrorism

ABSTRACT. During and after disasters, pediatricians can assist parents and community leaders not only by accommodating the unique needs of children but also by being cognizant of the psychological responses of children to reduce the possibility of long-term psychological morbidity. The effects of disaster on children are mediated by many factors including personal experience, parental reaction, developmental competency, gender, and the stage of disaster response. Pediatricians can be effective advocates for the child and family and at the community level and can affect national policy in support of families. In this report, specific children's responses are delineated,

risk factors for adverse reactions are discussed, and advice is given for pediatricians to ameliorate the effects of disaster on children. (9/05)

PSYCHOSOCIAL RISKS OF CHRONIC HEALTH CONDITIONS IN CHILDHOOD AND ADOLESCENCE

Committee on Children With Disabilities and Committee on Psychosocial Aspects of Child and Family Health (12/93, reaffirmed 10/96)

PSYCHOSOCIAL SUPPORT FOR YOUTH LIVING WITH HIV (CLINICAL REPORT)

Jaime Martinez, MD, FAAP; Rana Chakraborty, MD, FAAP; and Committee on Pediatric AIDS

ABSTRACT. This clinical report provides guidance for the pediatrician in addressing the psychosocial needs of adolescents and young adults living with HIV, which can improve linkage to care and adherence to life-saving antiretroviral (ARV) therapy. Recent national case surveillance data for youth (defined here as adolescents and young adults 13 to 24 years of age) revealed that the burden of HIV/AIDS fell most heavily and disproportionately on African American youth, particularly males having sex with males. To effectively increase linkage to care and sustain adherence to therapy, interventions should address the immediate drivers of ARV compliance and also address factors that provide broader social and structural support for HIV-infected adolescents and young adults. Interventions should address psychosocial development, including lack of future orientation, inadequate educational attainment and limited health literacy, failure to focus on the long-term consequences of near-term risk behaviors, and coping ability. Associated challenges are closely linked to the structural environment. Individual case management is essential to linkage to and retention in care, ARV adherence, and management of associated comorbidities. Integrating these skills into pediatric and adolescent HIV practice in a medical home setting is critical, given the alarming increase in new HIV infections in youth in the United States. (2/14)

See full text on page 917.

QUALITY EARLY EDUCATION AND CHILD CARE FROM BIRTH TO KINDERGARTEN

Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. High-quality early education and child care for young children improves their health and promotes their development and learning. Early education includes all of a child's experiences at home, in child care, and in other preschool settings. Pediatricians have a role in promoting access to quality early education and child care beginning at birth for all children. The American Academy of Pediatrics affords pediatricians the opportunity to promote the educational and socioemotional needs of young children with other advocacy groups. (1/05, reaffirmed 12/09)

RABIES-PREVENTION POLICY UPDATE: NEW REDUCED-DOSE SCHEDULE

Committee on Infectious Diseases

ABSTRACT. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention recommends reducing the number of doses from 5 to 4 of human diploid cell vaccine or purified chick embryo cell vaccine required for postexposure prophylaxis to prevent rabies in humans. The vaccine doses should be given on day 0 (first day of prophylaxis) and days 3, 7, and 14 after the first dose. For persons with immune suppression, the 5-dose regimen should continue to be used. Recommendations for the use of human rabies immunoglobulin remain unchanged. The American Academy of Pediatrics endorses these recommendations. (3/11)

RACE/ETHNICITY, GENDER, SOCIOECONOMIC STATUS—RESEARCH EXPLORING THEIR EFFECTS ON CHILD HEALTH: A SUBJECT REVIEW (CLINICAL REPORT)

Committee on Pediatric Research

ABSTRACT. Data on research participants and populations frequently include race, ethnicity, and gender as categorical variables, with the assumption that these variables exert their effects through innate or genetically determined biologic mechanisms. There is a growing body of research that suggests, however, that these variables have strong social dimensions that influence health. Socioeconomic status, a complicated construct in its own right, interacts with and confounds analyses of race/ethnicity and gender. The Academy recommends that research studies include race/ethnicity, gender, and socioeconomic status as explanatory variables only when data relevant to the underlying social mechanisms have been collected and included in the analyses. (6/00, reaffirmed 10/05, 1/09)

RACIAL AND ETHNIC DISPARITIES IN THE HEALTH AND HEALTH CARE OF CHILDREN (TECHNICAL REPORT)

Glenn Flores, MD, and Committee on Pediatric Research

ABSTRACT. *Objective.* This technical report reviews and synthesizes the published literature on racial/ethnic disparities in children's health and health care.

Methods. A systematic review of the literature was conducted for articles published between 1950 and March 2007. Inclusion criteria were peer-reviewed, original research articles in English on racial/ethnic disparities in the health and health care of US children. Search terms used included "child," "disparities," and the Index Medicus terms for each racial/ethnic minority group.

Results. Of 781 articles initially reviewed, 111 met inclusion criteria and constituted the final database. Review of the literature revealed that racial/ethnic disparities in children's health and health care are quite extensive, pervasive, and persistent. Disparities were noted across the spectrum of health and health care, including in mortality rates, access to care and use of services, prevention and population health, health status, adolescent health, chronic diseases, special health care needs, quality of care, and organ transplantation. Mortality-rate disparities were noted for children in all 4 major US racial/ethnic minority groups, including substantially greater risks than white children of all-cause mortality; death from

drowning, from acute lymphoblastic leukemia, and after congenital heart defect surgery; and an earlier median age at death for those with Down syndrome and congenital heart defects. Certain methodologic flaws were commonly observed among excluded studies, including failure to evaluate children separately from adults (22%), combining all nonwhite children into 1 group (9%), and failure to provide a white comparison group (8%). Among studies in the final database, 22% did not perform multivariable or stratified analyses to ensure that disparities persisted after adjustment for potential confounders.

Conclusions. Racial/ethnic disparities in children's health and health care are extensive, pervasive, and persistent, and occur across the spectrum of health and health care. Methodologic flaws were identified in how such disparities are sometimes documented and analyzed. Optimal health and health care for all children will require recognition of disparities as pervasive problems, methodologically sound disparities studies, and rigorous evaluation of disparities interventions. (3/10, reaffirmed 5/13)

RADIATION DISASTERS AND CHILDREN

Committee on Environmental Health

ABSTRACT. The special medical needs of children make it essential that pediatricians be prepared for radiation disasters, including 1) the detonation of a nuclear weapon; 2) a nuclear power plant event that unleashes a radioactive cloud; and 3) the dispersal of radionuclides by conventional explosive or the crash of a transport vehicle. Any of these events could occur unintentionally or as an act of terrorism. Nuclear facilities (eg, power plants, fuel processing centers, and food irradiation facilities) are often located in highly populated areas, and as they age, the risk of mechanical failure increases. The short- and long-term consequences of a radiation disaster are significantly greater in children for several reasons. First, children have a disproportionately higher minute ventilation, leading to greater internal exposure to radioactive gases. Children have a significantly greater risk of developing cancer even when they are exposed to radiation in utero. Finally, children and the parents of young children are more likely than are adults to develop enduring psychologic injury after a radiation disaster. The pediatrician has a critical role in planning for radiation disasters. For example, potassium iodide is of proven value for thyroid protection but must be given before or soon after exposure to radioiodines, requiring its placement in homes, schools, and child care centers. Pediatricians should work with public health authorities to ensure that children receive full consideration in local planning for a radiation disaster. (6/03, reaffirmed 1/07)

RADIATION RISK TO CHILDREN FROM COMPUTED TOMOGRAPHY (CLINICAL REPORT)

Alan S. Brody, MD; Donald P. Frush, MD; Walter Huda,

PhD; Robert L. Brent, MD, PhD; and Section on Radiology

ABSTRACT. Imaging studies that use ionizing radiation are an essential tool for the evaluation of many disorders of childhood. Ionizing radiation is used in radiography, fluoroscopy, angiography, and computed tomography scanning. Computed tomography is of particular interest because of its relatively high radiation dose and wide use.

Consensus statements on radiation risk suggest that it is reasonable to act on the assumption that low-level radiation may have a small risk of causing cancer. The medical community should seek ways to decrease radiation exposure by using radiation doses as low as reasonably achievable and by performing these studies only when necessary. There is wide agreement that the benefits of an indicated computed tomography scan far outweigh the risks. Pediatric health care professionals' roles in the use of computed tomography on children include deciding when a computed tomography scan is necessary and discussing the risk with patients and families. Radiologists should be a source of consultation when forming imaging strategies and should create specific protocols with scanning techniques optimized for pediatric patients. Families and patients should be encouraged to ask questions about the risks and benefits of computed tomography scanning. The information in this report is provided to aid in decision-making and discussions with the health care team, patients, and families. (9/07)

RECOGNITION AND MANAGEMENT OF IATROGENICALLY INDUCED OPIOID DEPENDENCE AND WITHDRAWAL IN CHILDREN (CLINICAL REPORT)

Jeffrey Galinkin, MD, FAAP; Jeffrey Lee Koh, MD, FAAP;

Committee on Drugs; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Opioids are often prescribed to children for pain relief related to procedures, acute injuries, and chronic conditions. Round-the-clock dosing of opioids can produce opioid dependence within 5 days. According to a 2001 consensus paper from the American Academy of Pain Medicine, American Pain Society, and American Society of Addiction Medicine, dependence is defined as "a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist." Although the experience of many children undergoing iatrogenically induced withdrawal may be mild or goes unreported, there is currently no guidance for recognition or management of withdrawal for this population. Guidance on this subject is available only for adults and primarily for adults with substance use disorders. The guideline will summarize existing literature and provide readers with information currently not available in any single source specific for this vulnerable pediatric population. (12/13)

RECOGNIZING AND RESPONDING TO MEDICAL NEGLECT (CLINICAL REPORT)

Carole Jenny, MD, MBA, and Committee on Child Abuse and Neglect

ABSTRACT. A caregiver may fail to recognize or respond to a child's medical needs for a variety of reasons. An effective response by a health care professional to medical neglect requires a comprehensive assessment of the child's needs, the parents' resources, the parents' efforts to provide for the needs of the child, and options for ensuring optimal health for the child. Such an assessment requires clear, 2-way communication between the family and the health care professional. Physicians should

consider the least intrusive options for managing cases of medical neglect that ensure the health and safety of the child. (12/07, reaffirmed 1/11)

RECOMMENDATION FOR MANDATORY INFLUENZA IMMUNIZATION OF ALL HEALTH CARE PERSONNEL

Henry H. Bernstein, DO; Jeffrey R. Starke, MD; and

Committee on Infectious Diseases

ABSTRACT. The purpose of this statement is to recommend implementation of a mandatory influenza immunization policy for all health care personnel. Immunization of health care personnel is a critically important step to substantially reduce health care-associated influenza infections. Despite the efforts of many organizations to improve influenza immunization rates with the use of voluntary campaigns, influenza coverage among health care personnel remains unacceptably low. Mandatory influenza immunization for all health care personnel is ethically justified, necessary, and long overdue to ensure patient safety. (9/10)

RECOMMENDATIONS FOR ADMINISTERING HEPATITIS A VACCINE TO CONTACTS OF INTERNATIONAL ADOPTEES

Committee on Infectious Diseases

ABSTRACT. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the American Academy of Pediatrics (AAP) recommend routine administration of hepatitis A vaccine for household members and close contacts, including baby-sitters, when children are adopted from countries with high or intermediate rates of hepatitis A infection. This policy expands previous AAP recommendations to immunize travelers to countries who are seeking to adopt a child in countries with high or medium hepatitis A endemicity. All previously nonimmune unvaccinated people who anticipate close exposure to international adoptees during the 60 days after their arrival should receive hepatitis A immunization, ideally 2 or more weeks before the arrival of the adopted child. (9/11)

RECOMMENDATIONS FOR PREVENTION AND CONTROL OF INFLUENZA IN CHILDREN, 2014–2015

Committee on Infectious Diseases

ABSTRACT. The purpose of this statement is to update recommendations for routine use of seasonal influenza vaccine and antiviral medications for the prevention and treatment of influenza in children. The American Academy of Pediatrics recommends annual seasonal influenza immunization for all people 6 months and older, including all children and adolescents. Highlights for the upcoming 2014–2015 season include the following:

1. The influenza vaccine composition for the 2014–2015 season is unchanged from the 2013–2014 season.
2. Both trivalent and quadrivalent influenza vaccines are available in the United States for the 2014–2015 season.
3. Annual universal influenza immunization is indicated with either a trivalent or quadrivalent vaccine (no preference).

4. Live attenuated influenza vaccine (LAIV) should be considered for healthy children 2 through 8 years of age who have no contraindications or precautions to the intranasal vaccine. If LAIV is not readily available, inactivated influenza vaccine (IIV) should be used; vaccination should not be delayed to obtain LAIV.
5. The dosing algorithm for administration of influenza vaccine to children 6 months through 8 years of age reflects that virus strains in the vaccine have not changed from last season.

As always, pediatricians, nurses, and all other health care personnel should be immunized themselves and should promote influenza vaccine use and infection control measures. In addition, pediatricians should promptly identify clinical influenza infections to enable rapid antiviral treatment, when indicated, to reduce morbidity and mortality. (10/14)

See full text on page 925.

RECOMMENDATIONS FOR PREVENTIVE PEDIATRIC HEALTH CARE

Committee on Practice and Ambulatory Medicine and Bright

Futures Steering Committee

ABSTRACT. Each child and family is unique; therefore, these Recommendations for Preventive Pediatric Health Care are designed for the care of children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in satisfactory fashion. Additional visits may become necessary if circumstances suggest variations from normal.

Developmental, psychosocial, and chronic disease issues for children and adolescents may require frequent counseling and treatment visits separate from preventive care visits.

These guidelines represent a consensus by the American Academy of Pediatrics (AAP) and Bright Futures. The AAP continues to emphasize the great importance of continuity of care in comprehensive health supervision and the need to avoid fragmentation of care. (12/07, reaffirmed 1/11)

RECOMMENDATIONS FOR THE PREVENTION OF PERINATAL GROUP B STREPTOCOCCAL (GBS) DISEASE

Committee on Infectious Diseases and Committee on Fetus and Newborn

ABSTRACT. The Centers for Disease Control and Prevention (CDC) guidelines for the prevention of perinatal group B streptococcal (GBS) disease were initially published in 1996. The American Academy of Pediatrics (AAP) also published a policy statement on this topic in 1997. In 2002, the CDC published revised guidelines that recommended universal antenatal GBS screening; the AAP endorsed these guidelines and published recommendations based on them in the 2003 *Red Book*. Since then, the incidence of early-onset GBS disease in neonates has decreased by an estimated 80%. However, in 2010, GBS disease remained the leading cause of early-onset neonatal sepsis. The CDC issued revised guidelines in 2010 based on evaluation of data generated after 2002. These



revised and comprehensive guidelines, which have been endorsed by the AAP, reaffirm the major prevention strategy—universal antenatal GBS screening and intrapartum antibiotic prophylaxis for culture-positive and high-risk women—and include new recommendations for laboratory methods for identification of GBS colonization during pregnancy, algorithms for screening and intrapartum prophylaxis for women with preterm labor and premature rupture of membranes, updated prophylaxis recommendations for women with a penicillin allergy, and a revised algorithm for the care of newborn infants. The purpose of this policy statement is to review and discuss the differences between the 2002 and 2010 CDC guidelines that are most relevant for the practice of pediatrics. (8/11)

RECOMMENDATIONS FOR THE PREVENTION OF *STREPTOCOCCUS PNEUMONIAE* INFECTIONS IN INFANTS AND CHILDREN: USE OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV13) AND PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPSV23)

Committee on Infectious Diseases

ABSTRACT. Routine use of the 7-valent pneumococcal conjugate vaccine (PCV7), available since 2000, has resulted in a dramatic reduction in the incidence of invasive pneumococcal disease (IPD) attributable to serotypes of *Streptococcus pneumoniae* contained in the vaccine. However, IPD caused by nonvaccine pneumococcal serotypes has increased, and nonvaccine serotypes are now responsible for the majority of the remaining cases of IPD occurring in children. A 13-valent pneumococcal conjugate vaccine has been licensed by the US Food and Drug Administration, which, in addition to the 7 serotypes included in the original PCV7, contains the 6 pneumococcal serotypes responsible for 63% of IPD cases now occurring in children younger than 5 years. Because of the expanded coverage provided by PCV13, it will replace PCV7. This statement provides recommendations for (1) the transition from PCV7 to PCV13; (2) the routine use of PCV13 for healthy children and children with an underlying medical condition that increases the risk of IPD; (3) a supplemental dose of PCV13 for (a) healthy children 14 through 59 months of age who have completed the PCV7 series and (b) children 14 through 71 months of age with an underlying medical condition that increases the risk of IPD who have completed the PCV7 series; (4) “catch-up” immunization for children behind schedule; and (5) PCV13 for certain children at high risk from 6 through 18 years of age. In addition, recommendations for the use of pneumococcal polysaccharide vaccine for children at high risk of IPD are also updated. (5/10)

RECOMMENDED CHILDHOOD AND ADOLESCENT IMMUNIZATION SCHEDULE—UNITED STATES, 2015

Committee on Infectious Diseases (1/15)

See full text on page 945.

RED REFLEX EXAMINATION IN NEONATES, INFANTS, AND CHILDREN

Section on Ophthalmology (joint with American Association for Pediatric Ophthalmology and Strabismus, American Academy of Ophthalmology, and American Association of Certified Orthoptists)

ABSTRACT. Red reflex testing is an essential component of the neonatal, infant, and child physical examination. This statement, which is a revision of the previous policy statement published in 2002, describes the rationale for testing, the technique used to perform this examination, and the indications for referral to an ophthalmologist experienced in the examination of children. (12/08)

REDUCING INJURY RISK FROM BODY CHECKING IN BOYS' YOUTH ICE HOCKEY

Council on Sports Medicine and Fitness

ABSTRACT. Ice hockey is an increasingly popular sport that allows intentional collision in the form of body checking for males but not for females. There is a two- to threefold increased risk of all injury, severe injury, and concussion related to body checking at all levels of boys' youth ice hockey. The American Academy of Pediatrics reinforces the importance of stringent enforcement of rules to protect player safety as well as educational interventions to decrease unsafe tactics. To promote ice hockey as a lifelong recreational pursuit for boys, the American Academy of Pediatrics recommends the expansion of non-checking programs and the restriction of body checking to elite levels of boys' youth ice hockey, starting no earlier than 15 years of age. (5/14)

See full text on page 955.

REDUCING THE NUMBER OF DEATHS AND INJURIES FROM RESIDENTIAL FIRES

Committee on Injury and Poison Prevention

ABSTRACT. Smoke inhalation, severe burns, and death from residential fires are devastating events, most of which are preventable. In 1998, approximately 381 500 residential structure fires resulted in 3250 non-firefighter deaths, 17 175 injuries, and approximately \$4.4 billion in property loss. This statement reviews important prevention messages and intervention strategies related to residential fires. It also includes recommendations for pediatricians regarding office anticipatory guidance, work in the community, and support of regulation and legislation that could result in a decrease in the number of fire-related injuries and deaths to children. (6/00)

REDUCING THE RISK OF HIV INFECTION ASSOCIATED WITH ILLICIT DRUG USE

Committee on Pediatric AIDS

ABSTRACT. Substance abuse, specifically the use of illicit drugs that are administered intravenously, continues to play a role in the transmission of human immunodeficiency virus type 1 (HIV-1) among adolescents and young adults (youth). Risks of HIV-1 infection may result from direct exposure to contaminated blood through sharing of injection drug equipment and from unsafe sexual practices (while under the influence of drugs and/or in exchange for drugs). Reducing the risk of HIV-1 infection that is associated with illicit drug use requires prevention education and prompt engagement in treatment.

Providing patients with education, instruction on decontamination of used injection drug equipment, improved access to sterile syringes and needles, and postexposure prophylaxis may decrease their risk of acquiring HIV-1 infection. Pediatricians should assess risk behaviors as part of every health care encounter, including queries about tobacco, alcohol, and marijuana use. The risks and benefits of postexposure prophylaxis with antiretroviral drugs should be considered for youth with a single recent (within 72 hours) high-risk exposure to HIV-1 through sharing needles/syringes with an HIV-1-infected individual or having unprotected intercourse with an individual who engages in injection drug use. Such prophylaxis must be accompanied by risk-reduction counseling, appropriate referrals for treatment, and evaluation for pregnancy and associated sexually transmitted infections. There is an urgent need for more substance-abuse prevention and treatment programs, legislation that facilitates unencumbered access to sterile syringes, and expedient availability of reproductive health care services for sexually active youth, including voluntary HIV-1 counseling and testing. (2/06, reaffirmed 5/09, 5/12)

REFERRAL TO PEDIATRIC SURGICAL SPECIALISTS

Surgical Advisory Panel

ABSTRACT. The American Academy of Pediatrics, with the collaboration of the Surgical Sections of the American Academy of Pediatrics, has created referral recommendations intended to serve as voluntary practice parameters to assist general pediatricians in determining when and to whom to refer their patients for pediatric surgical specialty care. It is recognized that these recommendations may be difficult to implement, because communities vary in terms of access to major pediatric medical centers. Limited access does not negate the value of the recommendations, however, because the child who needs specialized surgical and anesthetic care is best served by the skills of the appropriate pediatric surgical team. Major congenital anomalies, malignancies, major trauma, and chronic illnesses (including those associated with preterm birth) in infants and children should be managed by pediatric medical subspecialists and pediatric surgical specialists at pediatric referral centers that can provide expertise in many areas, including the pediatric medical subspecialties and surgical specialties of pediatric radiology, pediatric anesthesiology, pediatric pathology, and pediatric intensive care. The optimal management of the child with complex problems, chronic illness, or disabilities requires coordination, communication, and cooperation of the pediatric surgical specialist with the child's primary care pediatrician or physician. (1/14)

See full text on page 965.

REIMBURSEMENT FOR FOODS FOR SPECIAL DIETARY USE

Committee on Nutrition

ABSTRACT. Foods for special dietary use are recommended by physicians for chronic diseases or conditions of childhood, including inherited metabolic diseases. Although many states have created legislation requiring reimbursement for foods for special dietary use, legisla-

tion is now needed to mandate consistent coverage and reimbursement for foods for special dietary use and related support services with accepted medical benefit for children with designated medical conditions. (5/03, reaffirmed 1/06)

RELIEF OF PAIN AND ANXIETY IN PEDIATRIC PATIENTS IN EMERGENCY MEDICAL SYSTEMS (CLINICAL REPORT)

Joel A. Fein, MD, MPH; William T. Zempsky, MD, MPH;

Joseph P. Cravero, MD; Committee on Pediatric Emergency Medicine; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Control of pain and stress for children is a vital component of emergency medical care. Timely administration of analgesia affects the entire emergency medical experience and can have a lasting effect on a child's and family's reaction to current and future medical care. A systematic approach to pain management and anxiolysis, including staff education and protocol development, can provide comfort to children in the emergency setting and improve staff and family satisfaction. (10/12)

RELIGIOUS OBJECTIONS TO MEDICAL CARE

Committee on Bioethics

ABSTRACT. Parents sometimes deny their children the benefits of medical care because of religious beliefs. In some jurisdictions, exemptions to child abuse and neglect laws restrict government action to protect children or seek legal redress when the alleged abuse or neglect has occurred in the name of religion. The American Academy of Pediatrics (AAP) believes that all children deserve effective medical treatment that is likely to prevent substantial harm or suffering or death. In addition, the AAP advocates that all legal interventions apply equally whenever children are endangered or harmed, without exemptions based on parental religious beliefs. To these ends, the AAP calls for the repeal of religious exemption laws and supports additional efforts to educate the public about the medical needs of children. (2/97, reaffirmed 10/00, 6/03, 10/06, 5/09)

RESPIRATORY SUPPORT IN PRETERM INFANTS AT BIRTH

Committee on Fetus and Newborn

ABSTRACT. Current practice guidelines recommend administration of surfactant at or soon after birth in preterm infants with respiratory distress syndrome. However, recent multicenter randomized controlled trials indicate that early use of continuous positive airway pressure with subsequent selective surfactant administration in extremely preterm infants results in lower rates of bronchopulmonary dysplasia/death when compared with treatment with prophylactic or early surfactant therapy. Continuous positive airway pressure started at or soon after birth with subsequent selective surfactant administration may be considered as an alternative to routine intubation with prophylactic or early surfactant administration in preterm infants. (12/13)

RESPONDING TO PARENTAL REFUSALS OF IMMUNIZATION OF CHILDREN (CLINICAL REPORT)

Douglas S. Diekema, MD, MPH, and Committee on Bioethics
ABSTRACT. The American Academy of Pediatrics strongly endorses universal immunization. However, for childhood immunization programs to be successful, parents must comply with immunization recommendations. The problem of parental refusal of immunization for children is an important one for pediatricians. The goal of this report is to assist pediatricians in understanding the reasons parents may have for refusing to immunize their children, review the limited circumstances under which parental refusals should be referred to child protective services agencies or public health authorities, and provide practical guidance to assist the pediatrician faced with a parent who is reluctant to allow immunization of his or her child. (5/05, reaffirmed 1/09, 11/12)

RESTRAINT USE ON AIRCRAFT

Committee on Injury and Poison Prevention

ABSTRACT. Occupant protection policies for children younger than 2 years on aircraft are inconsistent with all other national policies on safe transportation. Children younger than 2 years are not required to be restrained or secured on aircraft during takeoff, landing, and conditions of turbulence. They are permitted to be held on the lap of an adult. Preventable injuries and deaths have occurred in aircraft during survivable crashes and conditions of turbulence. The American Academy of Pediatrics recommends a mandatory federal requirement for restraint use for children on aircraft. The Academy further recommends that parents ensure that a seat is available for all children during aircraft transport and follow current recommendations for restraint use for all children. Physicians play a significant role in counseling families, advocating for public policy mandates, and encouraging technologic research that will improve protection of children in aircraft. (11/01, reaffirmed 5/05, 10/08)

RETURNING TO LEARNING FOLLOWING A CONCUSSION (CLINICAL REPORT)

Mark E. Halstead, MD, FAAP; Karen McAvoy, PsyD; Cynthia D. Devore, MD, FAAP; Rebecca Carl, MD, FAAP; Michael Lee, MD, FAAP; Kelsey Logan, MD, FAAP; Council on Sports Medicine and Fitness; and Council on School Health

ABSTRACT. Following a concussion, it is common for children and adolescents to experience difficulties in the school setting. Cognitive difficulties, such as learning new tasks or remembering previously learned material, may pose challenges in the classroom. The school environment may also increase symptoms with exposure to bright lights and screens or noisy cafeterias and hallways. Unfortunately, because most children and adolescents look physically normal after a concussion, school officials often fail to recognize the need for academic or environmental adjustments. Appropriate guidance and recommendations from the pediatrician may ease the transition back to the school environment and facilitate the recovery of the child or adolescent. This report serves to provide a better understanding of possible factors that may contrib-

ute to difficulties in a school environment after a concussion and serves as a framework for the medical home, the educational home, and the family home to guide the student to a successful and safe return to learning. (10/13)

RITUAL GENITAL CUTTING OF FEMALE MINORS

Board of Directors (6/10)

ROLE OF PEDIATRICIANS IN ADVOCATING LIFE SUPPORT TRAINING COURSES FOR PARENTS AND THE PUBLIC

Committee on Pediatric Emergency Medicine

ABSTRACT. Available literature suggests a need for both initial cardiopulmonary resuscitation basic life support training and refresher courses for parents and the public as well as health care professionals. The promotion of basic life support training courses that establish a pediatric chain of survival spanning from prevention of cardiac arrest and trauma to rehabilitative and follow-up care for victims of cardiopulmonary arrest is advocated in this policy statement and is the focus of an accompanying technical report. Immediate bystander cardiopulmonary resuscitation for victims of cardiac arrest improves survival for out-of-hospital cardiac arrest. Pediatricians will improve the chance of survival of children and adults who experience cardiac arrest by advocating for cardiopulmonary resuscitation training and participating in basic life support training courses as participants and instructors. (12/04, reaffirmed 5/07, 8/10, 8/13)

ROLE OF PEDIATRICIANS IN ADVOCATING LIFE SUPPORT TRAINING COURSES FOR PARENTS AND THE PUBLIC (TECHNICAL REPORT)

Lee A. Pyles, MD; Jane Knapp, MD; and Committee on Pediatric Emergency Medicine

ABSTRACT. Available literature suggests a need for both initial cardiopulmonary resuscitation training and refresher courses. The establishment of a pediatric chain of survival for victims of cardiopulmonary arrest is the focus of this technical report and is advocated in the accompanying policy statement. Immediate bystander cardiopulmonary resuscitation for victims of cardiac arrest improves survival for out-of-hospital cardiac arrest. Pediatricians will improve the chance of survival of children and adults who experience cardiac arrest by advocating for basic life support training and participating in basic life support courses as participants and teachers. (12/04, reaffirmed 5/07, 8/10, 1/14)

THE ROLE OF PRESCHOOL HOME-VISITING PROGRAMS IN IMPROVING CHILDREN'S DEVELOPMENTAL AND HEALTH OUTCOMES

Council on Community Pediatrics

ABSTRACT. Child health and developmental outcomes depend to a large extent on the capabilities of families to provide a nurturing, safe environment for their infants and young children. Unfortunately, many families have insufficient knowledge about parenting skills and an inadequate support system of friends, extended family, or professionals to help with or advise them regarding child rearing. Home-visiting programs offer a mechanism for ensuring that at-risk families have social support, linkage with public and private community services, and ongoing

health, developmental, and safety education. When these services are part of a system of high-quality well-child care linked or integrated with the pediatric medical home, they have the potential to mitigate health and developmental outcome disparities. This statement reviews the history of home visiting in the United States and reaffirms the support of the American Academy of Pediatrics for home-based parenting education and support. (1/09)

ROLE OF PULSE OXIMETRY IN EXAMINING NEWBORNS FOR CONGENITAL HEART DISEASE: A SCIENTIFIC STATEMENT FROM THE AHA AND AAP

William T. Mahle, MD; Jane W. Newburger, MD, MPH; G. Paul Matherne, MD; Frank C. Smith, MD; Tracey R. Hoke, MD; Robert Koppel, MD; Samuel S. Gidding, MD; Robert H. Beekman, III, MD; Scott D. Grosse, PhD; on behalf of Section on Cardiology and Cardiac Surgery and Committee of Fetus and Newborn (joint with American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research)

ABSTRACT. *Background.* The purpose of this statement is to address the state of evidence on the routine use of pulse oximetry in newborns to detect critical congenital heart disease (CCHD).

Methods and Results. A writing group appointed by the American Heart Association and the American Academy of Pediatrics reviewed the available literature addressing current detection methods for CCHD, burden of missed and/or delayed diagnosis of CCHD, rationale of oximetry screening, and clinical studies of oximetry in otherwise asymptomatic newborns. MEDLINE database searches from 1966 to 2008 were done for English-language papers using the following search terms: congenital heart disease, pulse oximetry, physical examination, murmur, echocardiography, fetal echocardiography, and newborn screening. The reference lists of identified papers were also searched. Published abstracts from major pediatric scientific meetings in 2006 to 2008 were also reviewed. The American Heart Association classification of recommendations and levels of evidence for practice guidelines were used. In an analysis of pooled studies of oximetry assessment performed after 24 hours of life, the estimated sensitivity for detecting CCHD was 69.6%, and the positive predictive value was 47.0%; however, sensitivity varied dramatically among studies from 0% to 100%. False-positive screens that required further evaluation occurred in only 0.035% of infants screened after 24 hours.

Conclusions. Currently, CCHD is not detected in some newborns until after their hospital discharge, which results in significant morbidity and occasional mortality. Furthermore, routine pulse oximetry performed on asymptomatic newborns after 24 hours of life, but before hospital discharge, may detect CCHD. Routine pulse oximetry performed after 24 hours in hospitals that have on-site pediatric cardiovascular services incurs very low cost and risk of harm. Future studies in larger populations and across a broad range of newborn delivery systems are needed to determine whether this practice should become standard of care in the routine assessment of the neonate. (8/09)

THE ROLE OF SCHOOLS IN COMBATING ILLICIT SUBSTANCE ABUSE

Council on School Health and Committee on Substance Abuse
ABSTRACT. Disturbingly high levels of illicit drug use remain a problem among American teenagers. As the physical, social, and psychological “home away from home” for most youth, schools naturally assume a primary role in substance abuse education, prevention, and early identification. However, the use of random drug testing on students as a component of drug prevention programs requires additional, more rigorous scientific evaluation. Widespread implementation should await the result of ongoing studies to address the effectiveness of testing and evaluate possible inadvertent harm. If drug testing on students is conducted, it should never be implemented in isolation. A comprehensive assessment and therapeutic management program for the student who tests positive should be in place before any testing is performed. Schools have the opportunity to work with parents, health care professionals, and community officials to use programs with proven effectiveness, to identify students who show behavioral risks for drug-related problems, and to make referrals to a student’s medical home. When use of an illicit substance is detected, schools can foster relationships with established health care experts to assist them. A student undergoing individualized intervention for using illicit substances merits privacy. This requires that awareness of the student’s situation be limited to parents, the student’s physician, and only those designated school health officials with a need to know. For the purposes of this statement, alcohol, tobacco, and inhalants are not addressed. (12/07)

ROLE OF THE MEDICAL HOME IN FAMILY-CENTERED EARLY INTERVENTION SERVICES

Council on Children With Disabilities

ABSTRACT. There is growing evidence that early intervention services have a positive influence on the developmental outcome of children with established disabilities as well as those who are considered to be “at risk” of disabilities. Various federal and state laws now mandate the establishment of community-based, coordinated, multidisciplinary, family-centered programs that are accessible to children and families. The medical home, in close collaboration with the family and the early intervention team, can play a critical role in ensuring that at-risk children receive appropriate clinical and developmental early intervention services. The purpose of this statement is to assist the pediatric health care professional in assuming a proactive role with the interdisciplinary team that provides early intervention services. (11/07)

THE ROLE OF THE PEDIATRICIAN IN RURAL EMERGENCY MEDICAL SERVICES FOR CHILDREN

Committee on Pediatric Emergency Medicine

ABSTRACT. In rural America, pediatricians can play a key role in the development, implementation, and ongoing supervision of emergency medical services for children (EMSC). Pediatricians may represent the only source of pediatric expertise for a large region and are a vital resource for rural physicians (eg, general and family practice, emergency medicine) and other rural health care

professionals (physician assistants, nurse practitioners, and emergency medical technicians), providing education about management and prevention of pediatric illness and injury; appropriate equipment for the acutely ill or injured child; and acute, chronic, and rehabilitative care. In addition to providing clinical expertise, the pediatrician may be involved in quality assurance, clinical protocol development, and advocacy, and may serve as a liaison between emergency medical services and other entities working with children (eg, school nurses, child care centers, athletic programs, and programs for children with special health care needs). (10/12)

ROLE OF THE PEDIATRICIAN IN YOUTH VIOLENCE PREVENTION

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Youth violence continues to be a serious threat to the health of children and adolescents in the United States. It is crucial that pediatricians clearly define their role and develop the appropriate skills to address this threat effectively. From a clinical perspective, pediatricians should become familiar with *Connected Kids: Safe, Strong, Secure*, the American Academy of Pediatrics' primary care violence prevention protocol. Using this material, practices can incorporate preventive education, screening for risk, and linkages to community-based counseling and treatment resources. As advocates, pediatricians may bring newly developed information regarding key risk factors such as exposure to firearms, teen dating violence, and bullying to the attention of local and national policy makers. This policy statement refines the developing role of pediatricians in youth violence prevention and emphasizes the importance of this issue in the strategic agenda of the American Academy of Pediatrics. (6/09)

ROLE OF THE SCHOOL NURSE IN PROVIDING SCHOOL HEALTH SERVICES

Council on School Health

ABSTRACT. The school nurse has a crucial role in the seamless provision of comprehensive health services to children and youth. Increasing numbers of students enter schools with chronic health conditions that require management during the school day. This policy statement describes for pediatricians the role of the school nurse in serving as a team member in providing preventive services, early identification of problems, interventions, and referrals to foster health and educational success. To optimally care for children, preparation, ongoing education, and appropriate staffing levels of school nurses are important factors for success. Recommendations are offered to facilitate the working relationship between the school nurse and the child's medical home. This statement has been endorsed by the National Association of School Nurses. (5/08)

ROLE OF THE SCHOOL PHYSICIAN

Council on School Health

ABSTRACT. The American Academy of Pediatrics recognizes the important role physicians play in promoting the optimal biopsychosocial well-being of children in the school setting. Although the concept of a school physician

has existed for more than a century, uniformity among states and school districts regarding physicians in schools and the laws governing it are lacking. By understanding the roles and contributions physicians can make to schools, pediatricians can support and promote school physicians in their communities and improve health and safety for children. (12/12)

SAFE TRANSPORTATION OF NEWBORNS AT HOSPITAL DISCHARGE

Committee on Injury and Poison Prevention

ABSTRACT. All hospitals should set policies that require the discharge of every newborn in a car safety seat that is appropriate for the infant's maturity and medical condition. Discharge policies for newborns should include a parent education component, regular review of educational materials, and periodic in-service education for responsible staff. Appropriate child restraint systems should become a benefit of coverage by Medicaid, managed care organizations, and other third-party insurers. (10/99, reaffirmed 1/03, 1/06, 10/08)

SAFE TRANSPORTATION OF PRETERM AND LOW BIRTH WEIGHT INFANTS AT HOSPITAL DISCHARGE (CLINICAL REPORT)

Marilyn J. Bull, MD; William A. Engle, MD; Committee on Injury, Violence, and Poison Prevention; and Committee on Fetus and Newborn

ABSTRACT. Safe transportation of preterm and low birth weight infants requires special considerations. Both physiologic immaturity and low birth weight must be taken into account to properly position such infants. This clinical report provides guidelines for pediatricians and other caregivers who counsel parents of preterm and low birth weight infants about car safety seats. (4/09, reaffirmed 8/13)

SCHOOL BUS TRANSPORTATION OF CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Committee on Injury and Poison Prevention (8/01, reaffirmed 1/05, 2/08, 5/13)

SCHOOL HEALTH ASSESSMENTS

Committee on School Health

ABSTRACT. Comprehensive health assessments often are performed in school-based clinics or public health clinics by health professionals other than pediatricians. Pediatricians or other physicians skilled in child health care should participate in such evaluations. This statement provides guidance on the scope of in-school health assessments and the roles of the pediatrician, school nurse, school, and community. (4/00, reaffirmed 6/03, 5/06, 10/11)

SCHOOL HEALTH CENTERS AND OTHER INTEGRATED SCHOOL HEALTH SERVICES

Committee on School Health

ABSTRACT. This statement offers guidelines on the integration of expanded school health services, including school-based and school-linked health centers, into community-based health care systems. Expanded school health services should be integrated so that they enhance accessibility, provide high-quality health care, link chil-

dren to a medical home, are financially sustainable, and address both long- and short-term needs of children and adolescents. (1/01)

SCHOOL READINESS (TECHNICAL REPORT)

Pamela C. High, MD; Committee on Early Childhood, Adoption, and Dependent Care; and Council on School Health

ABSTRACT. School readiness includes the readiness of the individual child, the school's readiness for children, and the ability of the family and community to support optimal early child development. It is the responsibility of schools to be ready for all children at all levels of readiness. Children's readiness for kindergarten should become an outcome measure for community-based programs, rather than an exclusion criterion at the beginning of the formal educational experience. Our new knowledge of early brain and child development has revealed that modifiable factors in a child's early experience can greatly affect that child's learning trajectory. Many US children enter kindergarten with limitations in their social, emotional, cognitive, and physical development that might have been significantly diminished or eliminated through early identification of and attention to child and family needs. Pediatricians have a role in promoting school readiness for all children, beginning at birth, through their practices and advocacy. The American Academy of Pediatrics affords pediatricians many opportunities to promote the physical, social-emotional, and educational health of young children, with other advocacy groups. This technical report supports American Academy of Pediatrics policy statements "Quality Early Education and Child Care From Birth to Kindergarten" and "The Inappropriate Use of School 'Readiness' Tests." (4/08, reaffirmed 9/13)

SCHOOL START TIMES FOR ADOLESCENTS

Adolescent Sleep Working Group, Committee on Adolescence, and Council on School Health

ABSTRACT. The American Academy of Pediatrics recognizes insufficient sleep in adolescents as an important public health issue that significantly affects the health and safety, as well as the academic success, of our nation's middle and high school students. Although a number of factors, including biological changes in sleep associated with puberty, lifestyle choices, and academic demands, negatively affect middle and high school students' ability to obtain sufficient sleep, the evidence strongly implicates earlier school start times (ie, before 8:30 AM) as a key modifiable contributor to insufficient sleep, as well as circadian rhythm disruption, in this population. Furthermore, a substantial body of research has now demonstrated that delaying school start times is an effective countermeasure to chronic sleep loss and has a wide range of potential benefits to students with regard to physical and mental health, safety, and academic achievement. The American Academy of Pediatrics strongly supports the efforts of school districts to optimize sleep in students and urges high schools and middle schools to aim for start times that allow students the opportunity to achieve optimal levels of sleep (8.5–9.5 hours) and to improve physical (eg, reduced obesity risk) and mental (eg, lower rates of

depression) health, safety (eg, drowsy driving crashes), academic performance, and quality of life. (8/14)

See full text on page 975.

SCHOOL TRANSPORTATION SAFETY

Committee on Injury, Violence, and Poison Prevention and Council on School Health

ABSTRACT. This policy statement replaces the previous version published in 1996. It provides new information, studies, regulations, and recommendations related to the safe transportation of children to and from school and school-related activities. Pediatricians can play an important role at the patient/family, community, state, and national levels as child advocates and consultants to schools and early education programs about transportation safety. (7/07, reaffirmed 10/11)

SCHOOL-BASED HEALTH CENTERS AND PEDIATRIC PRACTICE

Council on School Health

ABSTRACT. School-based health centers (SBHCs) have become an important method of health care delivery for the youth of our nation. Although they only represent 1 aspect of a coordinated school health program approach, SBHCs have provided access to health care services for youth confronted with age, financial, cultural, and geographic barriers. A fundamental principle of SBHCs is to create an environment of service coordination and collaboration that addresses the health needs and well-being of youth with health disparities or poor access to health care services. Some pediatricians have concerns that these centers are in conflict with the primary care provider's medical home. This policy provides an overview of SBHCs and some of their documented benefits, addresses the issue of potential conflict with the medical home, and provides recommendations that support the integration and coordination of SBHCs and the pediatric medical home practice. (1/12)

SCHOOL-BASED MENTAL HEALTH SERVICES

Committee on School Health

ABSTRACT. More than 20% of children and adolescents have mental health problems. Health care professionals for children and adolescents must educate key stakeholders about the extent of these problems and work together with them to increase access to mental health resources. School-based programs offer the promise of improving access to diagnosis of and treatment for the mental health problems of children and adolescents. Pediatric health care professionals, educators, and mental health specialists should work in collaboration to develop and implement effective school-based mental health services. (6/04, reaffirmed 5/09)

SCOPE OF HEALTH CARE BENEFITS FOR CHILDREN FROM BIRTH THROUGH AGE 26

Committee on Child Health Financing

ABSTRACT. The optimal health of all children is best achieved with access to appropriate and comprehensive health care benefits. This policy statement outlines and defines the recommended set of health insurance benefits for children through age 26. The American Academy of Pediatrics developed a set of recommendations concern-

ing preventive care services for children, adolescents, and young adults. These recommendations are compiled in the publication *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, third edition. The Bright Futures recommendations were referenced as a standard for access and design of age-appropriate health insurance benefits for infants, children, adolescents, and young adults in the Patient Protection and Affordable Care Act of 2010 (Pub L No. 114-148). (11/11)

SCOPE OF PRACTICE ISSUES IN THE DELIVERY OF PEDIATRIC HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. The American Academy of Pediatrics (AAP) believes that optimal pediatric health care depends on a team-based approach with supervision by a physician leader, preferably a pediatrician. The pediatrician, here defined to include not only pediatric generalists but all pediatric medical subspecialists, all surgical specialists, and internal medicine/pediatric physicians, is uniquely qualified to manage, coordinate, and supervise the entire spectrum of pediatric care, from diagnosis through all stages of treatment, in all practice settings. The AAP recognizes the valuable contributions of nonphysician clinicians, including nurse practitioners and physician assistants, in delivering optimal pediatric care. However, the expansion of the scope of practice of nonphysician pediatric clinicians raises critical public policy and child health advocacy concerns. Pediatricians should serve as advocates for optimal pediatric care in state legislatures, public policy forums, and the media and should pursue opportunities to resolve scope of practice conflicts outside state legislatures. The AAP affirms the importance of appropriate documentation and standards in pediatric education, training, skills, clinical competencies, examination, regulation, and patient care to ensure safety and quality health care for all infants, children, adolescents, and young adults. (5/13)

SCREENING EXAMINATION OF PREMATURE INFANTS FOR RETINOPATHY OF PREMATURITY

Section on Ophthalmology (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. This statement revises a previous statement on screening of preterm infants for retinopathy of prematurity (ROP) that was published in 2006. ROP is a pathologic process that occurs only in immature retinal tissue and can progress to a tractional retinal detachment, which can result in functional or complete blindness. Use of peripheral retinal ablative therapy by using laser photocoagulation for nearly 2 decades has resulted in a high probability of markedly decreasing the incidence of this poor visual outcome, but the sequential nature of ROP creates a requirement that at-risk preterm infants be examined at proper times and intervals to detect the changes of ROP before they become permanently destructive. This statement presents the attributes on which an effective program for detecting and treating ROP could be based, including the timing of initial examination and subsequent reexamination intervals. (12/12)

SCREENING FOR NONVIRAL SEXUALLY TRANSMITTED INFECTIONS IN ADOLESCENTS AND YOUNG ADULTS

Committee on Adolescence (joint with Society for Adolescent Health and Medicine)

ABSTRACT. Prevalence rates of many sexually transmitted infections (STIs) are highest among adolescents. If nonviral STIs are detected early, they can be treated, transmission to others can be eliminated, and sequelae can be averted. The US Preventive Services Task Force and the Centers for Disease Control and Prevention have published chlamydia, gonorrhea, and syphilis screening guidelines that recommend screening those at risk on the basis of epidemiologic and clinical outcomes data. This policy statement specifically focuses on these curable, nonviral STIs and reviews the evidence for nonviral STI screening in adolescents, communicates the value of screening, and outlines recommendations for routine nonviral STI screening of adolescents. (6/14)

See full text on page 985.

SCREENING FOR RETINOPATHY IN THE PEDIATRIC PATIENT WITH TYPE 1 DIABETES MELLITUS (CLINICAL REPORT)

Gregg T. Lueder, MD; Janet Silverstein, MD; Section on Ophthalmology; and Section on Endocrinology (joint with American Association for Pediatric Ophthalmology and Strabismus)

ABSTRACT. Diabetic retinopathy (DR) is the leading cause of blindness in young adults in the United States. Early identification and treatment of DR can decrease the risk of vision loss in affected patients. This clinical report reviews the risk factors for the development of DR and screening guidance for pediatric patients with type 1 diabetes mellitus. (7/05, reaffirmed 1/09, 7/14)

SECONDHAND AND PRENATAL TOBACCO SMOKE EXPOSURE (TECHNICAL REPORT)

Dana Best, MD, MPH; Committee on Environmental Health; Committee on Native American Child Health; and Committee on Adolescence

ABSTRACT. Secondhand tobacco smoke (SHS) exposure of children and their families causes significant morbidity and mortality. In their personal and professional roles, pediatricians have many opportunities to advocate for elimination of SHS exposure of children, to counsel tobacco users to quit, and to counsel children never to start. This report discusses the harms of tobacco use and SHS exposure, the extent and costs of tobacco use and SHS exposure, and the evidence that supports counseling and other clinical interventions in the cycle of tobacco use. Recommendations for future research, policy, and clinical practice change are discussed. To improve understanding and provide support for these activities, the harms of SHS exposure are discussed, effective ways to eliminate or reduce SHS exposure are presented, and policies that support a smoke-free environment are outlined. (10/09, reaffirmed 5/14)

SELECTING APPROPRIATE TOYS FOR YOUNG CHILDREN: THE PEDIATRICIAN'S ROLE (CLINICAL REPORT)

Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. Play is essential for learning in children. Toys are the tools of play. Which play materials are provided

and how they are used are equally important. Adults caring for children can be reminded that toys facilitate but do not substitute for the most important aspect of nurture—warm, loving, dependable relationships. Toys should be safe, affordable, and developmentally appropriate. Children do not need expensive toys. Toys should be appealing to engage the child over a period of time. Information and resources are provided in this report so pediatricians can give parents advice about selecting toys. (4/03, reaffirmed 10/06, 5/11)

SELF-INJECTABLE EPINEPHRINE FOR FIRST-AID MANAGEMENT OF ANAPHYLAXIS (CLINICAL REPORT)

Scott H. Sicherer, MD; F. Estelle R. Simons, MD; and Section on Allergy and Immunology

ABSTRACT. Anaphylaxis is a severe, potentially fatal systemic allergic reaction that is rapid in onset and may cause death. Epinephrine is the primary medical therapy, and it must be administered promptly. This clinical report focuses on practical issues concerning the administration of self-injectable epinephrine for first-aid treatment of anaphylaxis in the community. The recommended epinephrine dose for anaphylaxis in children, based primarily on anecdotal evidence, is 0.01 mg/kg, up to 0.30 mg. Intramuscular injection of epinephrine into the lateral thigh (vastus lateralis) is the preferred route for therapy in first-aid treatment. Epinephrine autoinjectors are currently available in only 2 fixed doses: 0.15 and 0.30 mg. On the basis of current, albeit limited, data, it seems reasonable to recommend autoinjectors with 0.15 mg of epinephrine for otherwise healthy young children who weigh 10 to 25 kg (22–55 lb) and autoinjectors with 0.30 mg of epinephrine for those who weigh approximately 25 kg (55 lb) or more; however, specific clinical circumstances must be considered in these decisions. This report also describes several quandaries in regard to management, including the selection of dose, indications for prescribing an autoinjector, and decisions regarding when to inject epinephrine. Effective care for individuals at risk of anaphylaxis requires a comprehensive management approach involving families, allergic children, schools, camps, and other youth organizations. Risk reduction entails confirmation of the trigger, discussion of avoidance of the relevant allergen, a written individualized emergency anaphylaxis action plan, and education of supervising adults with regard to recognition and treatment of anaphylaxis. (3/07)

SENSORY INTEGRATION THERAPIES FOR CHILDREN WITH DEVELOPMENTAL AND BEHAVIORAL DISORDERS

Section on Complementary and Integrative Medicine and Council on Children With Disabilities

ABSTRACT. Sensory-based therapies are increasingly used by occupational therapists and sometimes by other types of therapists in treatment of children with developmental and behavioral disorders. Sensory-based therapies involve activities that are believed to organize the sensory system by providing vestibular, proprioceptive, auditory, and tactile inputs. Brushes, swings, balls, and other specially designed therapeutic or recreational equipment are used to provide these inputs. However, it is unclear whether children who present with sensory-based problems have an actual “disorder” of the sensory pathways of

the brain or whether these deficits are characteristics associated with other developmental and behavioral disorders. Because there is no universally accepted framework for diagnosis, sensory processing disorder generally should not be diagnosed. Other developmental and behavioral disorders must always be considered, and a thorough evaluation should be completed. Difficulty tolerating or processing sensory information is a characteristic that may be seen in many developmental behavioral disorders, including autism spectrum disorders, attention-deficit/hyperactivity disorder, developmental coordination disorders, and childhood anxiety disorders.

Occupational therapy with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive. Important roles for pediatricians and other clinicians may include discussing these limitations with parents, talking with families about a trial period of sensory integration therapy, and teaching families how to evaluate the effectiveness of a therapy. (5/12)

SEXUAL ORIENTATION AND ADOLESCENTS (CLINICAL REPORT)

Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics issued its first statement on homosexuality and adolescents in 1983, with a revision in 1993. This report reflects the growing understanding of youth of differing sexual orientations. Young people are recognizing their sexual orientation earlier than in the past, making this a topic of importance to pediatricians. Pediatricians should be aware that some youths in their care may have concerns about their sexual orientation or that of siblings, friends, parents, relatives, or others. Health care professionals should provide factual, current, nonjudgmental information in a confidential manner. All youths, including those who know or wonder whether they are not heterosexual, may seek information from physicians about sexual orientation, sexually transmitted diseases, substance abuse, or various psychosocial difficulties. The pediatrician should be attentive to various potential psychosocial difficulties, offer counseling or refer for counseling when necessary and ensure that every sexually active youth receives a thorough medical history, physical examination, immunizations, appropriate laboratory tests, and counseling about sexually transmitted diseases (including human immunodeficiency virus infection) and appropriate treatment if necessary.

Not all pediatricians may feel able to provide the type of care described in this report. Any pediatrician who is unable to care for and counsel nonheterosexual youth should refer these patients to an appropriate colleague. (6/04)

SEXUALITY, CONTRACEPTION, AND THE MEDIA

Victor C. Strasburger, MD, and Council on Communications and Media

ABSTRACT. From a health viewpoint, early sexual activity among US adolescents is a potential problem because of the risk of pregnancy and sexually transmitted infec-

tions. New evidence points to the media adolescents use frequently (television, music, movies, magazines, and the Internet) as important factors in the initiation of sexual intercourse. There is a major disconnect between what mainstream media portray—casual sex and sexuality with no consequences—and what children and teenagers need—straightforward information about human sexuality and the need for contraception when having sex. Television, film, music, and the Internet are all becoming increasingly sexually explicit, yet information on abstinence, sexual responsibility, and birth control remains rare. It is unwise to promote “abstinence-only” sex education when it has been shown to be ineffective and when the media have become such an important source of information about “nonabstinence.” Recommendations are presented to help pediatricians address this important issue. (8/10)

SEXUALITY EDUCATION FOR CHILDREN AND ADOLESCENTS

Committee on Psychosocial Aspects of Child and Family Health and Committee on Adolescence

ABSTRACT. Children and adolescents need accurate and comprehensive education about sexuality to practice healthy sexual behavior as adults. Early, exploitative, or risky sexual activity may lead to health and social problems, such as unintended pregnancy and sexually transmitted diseases, including human immunodeficiency virus infection and acquired immunodeficiency syndrome. This statement reviews the role of the pediatrician in providing sexuality education to children, adolescents, and their families. Pediatricians should integrate sexuality education into the confidential and longitudinal relationship they develop with children, adolescents, and families to complement the education children obtain at school and at home. Pediatricians must be aware of their own attitudes, beliefs, and values so their effectiveness in discussing sexuality in the clinical setting is not limited. (8/01, reaffirmed 10/04)

SEXUALITY OF CHILDREN AND ADOLESCENTS WITH DEVELOPMENTAL DISABILITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Ellen Roy Elias, MD; for Council on Children With Disabilities

ABSTRACT. Children and adolescents with developmental disabilities, like all children, are sexual persons. However, attention to their complex medical and functional issues often consumes time that might otherwise be invested in addressing the anatomic, physiologic, emotional, and social aspects of their developing sexuality. This report discusses issues of puberty, contraception, psychosexual development, sexual abuse, and sexuality education specific to children and adolescents with disabilities and their families. Pediatricians, in the context of the medical home, are encouraged to discuss issues of sexuality on a regular basis, ensure the privacy of each child and adolescent, promote self-care and social independence among persons with disabilities, advocate for appropriate sexuality education, and provide ongoing education for children and adolescents with developmental disabilities and their families. (7/06, reaffirmed 12/09, 7/13)

SHOPPING CART-RELATED INJURIES TO CHILDREN

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Shopping cart-related injuries to children are common and can result in severe injury or even death. Most injuries result from falls from carts or cart tip-overs, and injuries to the head and neck represent three fourths of cases. The current US standard for shopping carts should be revised to include clear and effective performance criteria to prevent falls from carts and cart tipovers. Pediatricians have an important role as educators, researchers, and advocates to promote the prevention of these injuries. (8/06, reaffirmed 4/09, 8/13)

SHOPPING CART-RELATED INJURIES TO CHILDREN (TECHNICAL REPORT)

Gary A. Smith, MD, DrPH, for Committee on Injury, Violence, and Poison Prevention

ABSTRACT. An estimated 24 200 children younger than 15 years, 20 700 (85%) of whom were younger than 5 years, were treated in US hospital emergency departments in 2005 for shopping cart-related injuries. Approximately 4% of shopping cart-related injuries to children younger than 15 years require admission to the hospital. Injuries to the head and neck represent three fourths of all injuries. Fractures account for 45% of all hospitalizations. Deaths have occurred from falls from shopping carts and cart tip-overs. Falls are the most common mechanism of injury and account for more than half of injuries associated with shopping carts. Cart tip-overs are the second most common mechanism, responsible for up to one fourth of injuries and almost 40% of shopping cart-related injuries among children younger than 2 years. Public-awareness initiatives, education programs, and parental supervision, although important, are not enough to prevent these injuries effectively. European Standard EN 1929-1:1998 and joint Australian/New Zealand Standard AS/NZS 3847.1:1999 specify requirements for the construction, performance, testing, and safety of shopping carts and have been implemented as national standards in 21 countries. A US performance standard for shopping carts (ASTM [American Society for Testing and Materials] F2372-04) was established in July 2004; however, it does not adequately address falls and cart tip-overs, which are the leading mechanisms of shopping cart-related injuries to children. The current US standard for shopping carts should be revised to include clear and effective performance criteria for shopping cart child-restraint systems and cart stability to prevent falls from carts and cart tip-overs. This is imperative to decrease the number and severity of shopping cart-related injuries to children. Recommendations from the American Academy of Pediatrics regarding prevention of shopping cart-related injuries are included in the accompanying policy statement. (8/06, reaffirmed 4/09, 8/13)

SIDS AND OTHER SLEEP-RELATED INFANT DEATHS: EXPANSION OF RECOMMENDATIONS FOR A SAFE INFANT SLEEPING ENVIRONMENT

Task Force on Sudden Infant Death Syndrome

ABSTRACT. Despite a major decrease in the incidence of sudden infant death syndrome (SIDS) since the American Academy of Pediatrics (AAP) released its recommenda-

tion in 1992 that infants be placed for sleep in a non-prone position, this decline has plateaued in recent years. Concurrently, other causes of sudden unexpected infant death that occur during sleep (sleep-related deaths), including suffocation, asphyxia, and entrapment, and ill-defined or unspecified causes of death have increased in incidence, particularly since the AAP published its last statement on SIDS in 2005. It has become increasingly important to address these other causes of sleep-related infant death. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. The AAP, therefore, is expanding its recommendations from focusing only on SIDS to focusing on a safe sleep environment that can reduce the risk of all sleep-related infant deaths, including SIDS. The recommendations described in this policy statement include supine positioning, use of a firm sleep surface, breastfeeding, room-sharing without bed-sharing, routine immunizations, consideration of using a pacifier, and avoidance of soft bedding, overheating, and exposure to tobacco smoke, alcohol, and illicit drugs. The rationale for these recommendations is discussed in detail in the accompanying "Technical Report—SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment." (10/11)

**SIDS AND OTHER SLEEP-RELATED INFANT DEATHS:
EXPANSION OF RECOMMENDATIONS FOR A SAFE
INFANT SLEEPING ENVIRONMENT (TECHNICAL REPORT)**

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SKATEBOARD AND SCOOTER INJURIES

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Skateboard-related injuries account for an estimated 50 000 emergency department visits and 1500 hospitalizations among children and adolescents in the United States each year. Nonpowered scooter-related injuries accounted for an estimated 9400 emergency department visits between January and August 2000, and 90% of these patients were children younger than 15 years. Many such injuries can be avoided if children and youth do not ride in traffic, if proper protective gear is worn, and if, in the absence of close adult supervision, skateboards and scooters are not used by children younger than 10 and 8 years, respectively. (3/02, reaffirmed 5/05, 10/08, 10/13)

SNOWMOBILING HAZARDS

Committee on Injury and Poison Prevention

ABSTRACT. Snowmobiles continue to pose a significant risk to children younger than 15 years and adolescents and young adults 15 through 24 years of age. Head injuries remain the leading cause of mortality and serious morbidity, arising largely from snowmobilers colliding, falling, or overturning during operation. Children also were injured while being towed in a variety of conveyances by snowmobiles. No uniform code of state laws governs the use of snowmobiles by children and youth. Because evidence is lacking to support the effectiveness of operator safety certification and because many children and adolescents do not have the required strength and skills to operate a snowmobile safely, the recreational operation of snowmobiles by persons younger than 16 years is not recommended. Snowmobiles should not be used to tow persons on a tube, tire, sled, or saucer. Furthermore, a graduated licensing program is advised for snowmobilers 16 years and older. Both active and passive snowmobile injury prevention strategies are suggested, as well as recommendations for manufacturers to make safer equipment for snowmobilers of all ages. (11/00, reaffirmed 5/04, 1/07, 6/10)

SOFT DRINKS IN SCHOOLS

Committee on School Health

ABSTRACT. This statement is intended to inform pediatricians and other health care professionals, parents, superintendents, and school board members about nutritional concerns regarding soft drink consumption in schools. Potential health problems associated with high intake of sweetened drinks are 1) overweight or obesity attributable to additional calories in the diet; 2) displacement of milk consumption, resulting in calcium deficiency with an attendant risk of osteoporosis and fractures; and 3) dental caries and potential enamel erosion. Contracts with school districts for exclusive soft drink rights encourage consumption directly and indirectly. School officials and parents need to become well informed about the health implications of vended drinks in school before making a decision about student access to them. A clearly defined, district-wide policy that restricts the sale of soft drinks will safeguard against health problems as a result of overconsumption. (1/04, reaffirmed 1/09)

SPECIAL REQUIREMENTS OF ELECTRONIC HEALTH RECORD SYSTEMS IN PEDIATRICS (CLINICAL REPORT)

S. Andrew Spooner, MD, MS, and Council on Clinical Information Technology

ABSTRACT. Some functions of an electronic health record system are much more important in providing pediatric care than in adult care. Pediatricians commonly complain about the absence of these “pediatric functions” when they are not available in electronic health record systems. To stimulate electronic health record system vendors to recognize and incorporate pediatric functionality into pediatric electronic health record systems, this clinical report reviews the major functions of importance to child health care providers. Also reviewed are important but less critical functions, any of which might be of major importance in a particular clinical context. The major areas described here are immunization management, growth tracking, medication dosing, data norms, and privacy in special pediatric populations. The American Academy of Pediatrics believes that if the functions described in this document are supported in all electronic health record systems, these systems will be more useful for patients of all ages. (3/07, reaffirmed 5/12)

SPECTRUM OF NONINFECTIOUS HEALTH EFFECTS FROM MOLDS

Committee on Environmental Health

ABSTRACT. Molds are eukaryotic (possessing a true nucleus) nonphotosynthetic organisms that flourish both indoors and outdoors. For humans, the link between mold exposure and asthma exacerbations, allergic rhinitis, infections, and toxicities from ingestion of mycotoxin-contaminated foods are well known. However, the cause-and-effect relationship between inhalational exposure to mold and other untoward health effects (eg, acute idiopathic pulmonary hemorrhage in infants and other illnesses and health complaints) requires additional investigation. Pediatricians play an important role in the education of families about mold, its adverse health effects, exposure prevention, and remediation procedures. (12/06, reaffirmed 1/11)

SPECTRUM OF NONINFECTIOUS HEALTH EFFECTS FROM MOLDS (TECHNICAL REPORT)

Lynnette J. Mazur, MD, MPH; Janice Kim, MD, PhD, MPH; and Committee on Environmental Health

ABSTRACT. Molds are multicellular fungi that are ubiquitous in outdoor and indoor environments. For humans, they are both beneficial (for the production of antimicrobial agents, chemotherapeutic agents, and vitamins) and detrimental. Exposure to mold can occur through inhalation, ingestion, and touching moldy surfaces. Adverse health effects may occur through allergic, infectious, irritant, or toxic processes. The cause-and-effect relationship between mold exposure and allergic and infectious illnesses is well known. Exposures to toxins via the gastrointestinal tract also are well described. However, the cause-and-effect relationship between inhalational exposure to mold toxins and other untoward health effects (eg, acute idiopathic pulmonary hemorrhage in infants and other illnesses and health complaints) is controversial and requires additional investigation. In this report we exam-

ine evidence of fungal-related illnesses and the unique aspects of mold exposure to children. Mold-remediation procedures are also discussed. (12/06, reaffirmed 1/11)

SPORT-RELATED CONCUSSION IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Mark E. Halstead, MD; Kevin D. Walter, MD; and Council on Sports Medicine and Fitness

ABSTRACT. Sport-related concussion is a “hot topic” in the media and in medicine. It is a common injury that is likely underreported by pediatric and adolescent athletes. Football has the highest incidence of concussion, but girls have higher concussion rates than boys do in similar sports. A clear understanding of the definition, signs, and symptoms of concussion is necessary to recognize it and rule out more severe intracranial injury. Concussion can cause symptoms that interfere with school, social and family relationships, and participation in sports. Recognition and education are paramount, because although proper equipment, sport technique, and adherence to rules of the sport may decrease the incidence or severity of concussions, nothing has been shown to prevent them. Appropriate management is essential for reducing the risk of long-term symptoms and complications. Cognitive and physical rest is the mainstay of management after diagnosis, and neuropsychological testing is a helpful tool in the management of concussion. Return to sport should be accomplished by using a progressive exercise program while evaluating for any return of signs or symptoms. This report serves as a basis for understanding the diagnosis and management of concussion in children and adolescent athletes. (8/10, reaffirmed 8/14)

SPORTS DRINKS AND ENERGY DRINKS FOR CHILDREN AND ADOLESCENTS: ARE THEY APPROPRIATE? (CLINICAL REPORT)

Committee on Nutrition and Council on Sports Medicine and Fitness

ABSTRACT. Sports and energy drinks are being marketed to children and adolescents for a wide variety of inappropriate uses. Sports drinks and energy drinks are significantly different products, and the terms should not be used interchangeably. The primary objectives of this clinical report are to define the ingredients of sports and energy drinks, categorize the similarities and differences between the products, and discuss misuses and abuses. Secondary objectives are to encourage screening during annual physical examinations for sports and energy drink use, to understand the reasons why youth consumption is widespread, and to improve education aimed at decreasing or eliminating the inappropriate use of these beverages by children and adolescents. Rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents. Furthermore, frequent or excessive intake of caloric sports drinks can substantially increase the risk for overweight or obesity in children and adolescents. Discussion regarding the appropriate use of sports drinks in the youth athlete who participates regularly in endurance or high-intensity sports and vigorous physical activity is beyond the scope of this report. (5/11)

STANDARD TERMINOLOGY FOR FETAL, INFANT, AND PERINATAL DEATHS (CLINICAL REPORT)

CAPT Wanda Denise Barfield, MD, MPH, and Committee on Fetus and Newborn

ABSTRACT. Accurately defining and reporting perinatal deaths (ie, fetal and infant deaths) is a critical first step in understanding the magnitude and causes of these important events. In addition to obstetric health care providers, neonatologists and pediatricians should know the current US definitions and reporting requirements for live births, fetal deaths, and infant deaths. Correct identification of these vital events will improve our local, state, and national data so that these deaths can be better addressed and reduced. (6/11)

STANDARDS FOR HEALTH INFORMATION TECHNOLOGY TO ENSURE ADOLESCENT PRIVACY

Committee on Adolescence and Council on Clinical Information Technology

ABSTRACT. Privacy and security of health information is a basic expectation of patients. Despite the existence of federal and state laws safeguarding the privacy of health information, health information systems currently lack the capability to allow for protection of this information for minors. This policy statement reviews the challenges to privacy for adolescents posed by commercial health information technology systems and recommends basic principles for ideal electronic health record systems. This policy statement has been endorsed by the Society for Adolescent Health and Medicine. (10/12)

STANDARDS FOR PEDIATRIC CANCER CENTERS

Section on Hematology/Oncology

ABSTRACT. Since the American Academy of Pediatrics published guidelines for pediatric cancer centers in 1986, 1997, and 2004, significant changes in the delivery of health care have prompted a review of the role of medical centers in the care of pediatric patients. The potential effect of these changes on the treatment and survival rates of children with cancer led to this revision. The intent of this statement is to delineate personnel, capabilities, and facilities that are essential to provide state-of-the-art care for children, adolescents, and young adults with cancer. This statement emphasizes the importance of board-certified pediatric hematologists/oncologists and appropriately qualified pediatric medical subspecialists and pediatric surgical specialists overseeing patient care and the need for specialized facilities as essential for the initial management and much of the follow-up for pediatric, adolescent, and young adult patients with cancer. For patients without practical access to a pediatric cancer center, care may be provided locally by a primary care physician or adult oncologist but at the direction of a pediatric oncologist. (7/14)

See full on text on page 997.

STATE CHILDREN'S HEALTH INSURANCE PROGRAM ACHIEVEMENTS, CHALLENGES, AND POLICY RECOMMENDATIONS

Committee on Child Health Financing

ABSTRACT. This policy statement reviews the impressive progress of the State Children's Health Insurance Program since its enactment in 1997 and identifies outstanding

challenges and state and federal policy recommendations. The American Academy of Pediatrics urges Congress to reauthorize SCHIP to strengthen its historic gains. The following set of recommended strategies for reauthorization pertain to funding, eligibility and enrollment, coverage, cost sharing, payment and provider-network capacity, and quality performance. (6/07)

STRATEGIES FOR PREVENTION OF HEALTH CARE-ASSOCIATED INFECTIONS IN THE NICU (CLINICAL REPORT)

Richard A. Polin, MD; Susan Denson, MD; Michael T. Brady, MD; Committee on Fetus and Newborn; and Committee on Infectious Diseases

ABSTRACT. Health care-associated infections in the NICU result in increased morbidity and mortality, prolonged lengths of stay, and increased medical costs. Neonates are at high risk of acquiring health care-associated infections because of impaired host-defense mechanisms, limited amounts of protective endogenous flora on skin and mucosal surfaces at time of birth, reduced barrier function of their skin, use of invasive procedures and devices, and frequent exposure to broad-spectrum antibiotic agents. This clinical report reviews management and prevention of health care-associated infections in newborn infants. (3/12)

STRENGTH TRAINING BY CHILDREN AND ADOLESCENTS

Council on Sports Medicine and Fitness

ABSTRACT. Pediatricians are often asked to give advice on the safety and efficacy of strength-training programs for children and adolescents. This statement, which is a revision of a previous American Academy of Pediatrics policy statement, defines relevant terminology and provides current information on risks and benefits of strength training for children and adolescents. (4/08, reaffirmed 6/11)

SUBSTANCE USE SCREENING, BRIEF INTERVENTION, AND REFERRAL TO TREATMENT FOR PEDIATRICIANS

Committee on Substance Abuse

ABSTRACT. As a component of comprehensive pediatric care, adolescents should receive appropriate guidance regarding substance use during routine clinical care. This statement addresses practitioner challenges posed by the spectrum of pediatric substance use and presents an algorithm-based approach to augment the pediatrician's confidence and abilities related to substance use screening, brief intervention, and referral to treatment in the primary care setting. Adolescents with addictions should be managed collaboratively (or comanaged) with child and adolescent mental health or addiction specialists. This statement reviews recommended referral guidelines that are based on established patient-treatment-matching criteria and the risk level for substance abuse. (10/11)

SUICIDE AND SUICIDE ATTEMPTS IN ADOLESCENTS (CLINICAL REPORT)

Benjamin N. Shain, MD, PhD, and Committee on Adolescence

ABSTRACT. Suicide is the third-leading cause of death for adolescents 15 to 19 years old. Pediatricians can take steps to help reduce the incidence of adolescent suicide by

screening for depression and suicidal ideation and behavior. This report updates the previous statement of the American Academy of Pediatrics and is intended to assist the pediatrician in the identification and management of the adolescent at risk of suicide. The extent to which pediatricians provide appropriate care for suicidal adolescents depends on their knowledge, skill, comfort with the topic, and ready access to appropriate community resources. All teenagers with suicidal thoughts or behaviors should know that their pleas for assistance are heard and that pediatricians are willing to serve as advocates to help resolve the crisis. (9/07)

SUPPLEMENTAL SECURITY INCOME (SSI) FOR CHILDREN AND YOUTH WITH DISABILITIES

Council on Children With Disabilities

ABSTRACT. The Supplemental Security Income (SSI) program remains an important source of financial support for low-income families of children with special health care needs and disabling conditions. In most states, SSI eligibility also qualifies children for the state Medicaid program, providing access to health care services. The Social Security Administration (SSA), which administers the SSI program, considers a child disabled under SSI if there is a medically determinable physical or mental impairment or combination of impairments that results in marked and severe functional limitations. The impairment(s) must be expected to result in death or have lasted or be expected to last for a continuous period of at least 12 months. The income and assets of families of children with disabilities are also considered when determining financial eligibility. When an individual with a disability becomes an adult at 18 years of age, the SSA considers only the individual's income and assets. The SSA considers an adult to be disabled if there is a medically determinable impairment (or combination of impairments) that prevents substantial gainful activity for at least 12 continuous months. SSI benefits are important for youth with chronic conditions who are transitioning to adulthood. The purpose of this statement is to provide updated information about the SSI medical and financial eligibility criteria and the disability-determination process. This statement also discusses how pediatricians can help children and youth when they apply for SSI benefits. (11/09)

SUPPORTING THE FAMILY AFTER THE DEATH OF A CHILD (CLINICAL REPORT)

Esther Wender, MD, and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. The death of a child can have a devastating effect on the family. The pediatrician has an important role to play in supporting the parents and any siblings still in his or her practice after such a death. Pediatricians may be poorly prepared to provide this support. Also, because of the pain of confronting the grief of family members, they may be reluctant to become involved. This statement gives guidelines to help the pediatrician provide such support. It describes the grief reactions that can be expected in family members after the death of a child. Ways of supporting family members are suggested, and other helpful resources in the community are described. The goal of this guidance is to prevent outcomes that may impair the

health and development of affected parents and children. (11/12)

SUPPORTING THE HEALTH CARE TRANSITION FROM ADOLESCENCE TO ADULTHOOD IN THE MEDICAL HOME (CLINICAL REPORT)



American Academy of Pediatrics, American Academy of Family Physicians, and American College of Physicians Transitions Clinical Report Authoring Group

ABSTRACT. Optimal health care is achieved when each person, at every age, receives medically and developmentally appropriate care. The goal of a planned health care transition is to maximize lifelong functioning and well-being for all youth, including those who have special health care needs and those who do not. This process includes ensuring that high-quality, developmentally appropriate health care services are available in an uninterrupted manner as the person moves from adolescence to adulthood. A well-timed transition from child- to adult-oriented health care is specific to each person and ideally occurs between the ages of 18 and 21 years. Coordination of patient, family, and provider responsibilities enables youth to optimize their ability to assume adult roles and activities. This clinical report represents expert opinion and consensus on the practice-based implementation of transition for all youth beginning in early adolescence. It provides a structure for training and continuing education to further understanding of the nature of adolescent transition and how best to support it. Primary care physicians, nurse practitioners, and physician assistants, as well as medical subspecialists, are encouraged to adopt these materials and make this process specific to their settings and populations. (7/11)

SURFACTANT REPLACEMENT THERAPY FOR PRETERM AND TERM NEONATES WITH RESPIRATORY DISTRESS (CLINICAL REPORT)

Richard A. Polin, MD, FAAP; Waldemar A. Carlo, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. Respiratory failure secondary to surfactant deficiency is a major cause of morbidity and mortality in preterm infants. Surfactant therapy substantially reduces mortality and respiratory morbidity for this population. Secondary surfactant deficiency also contributes to acute respiratory morbidity in late-preterm and term neonates with meconium aspiration syndrome, pneumonia/sepsis, and perhaps pulmonary hemorrhage; surfactant replacement may be beneficial for these infants. This statement summarizes the evidence regarding indications, administration, formulations, and outcomes for surfactant-replacement therapy. The clinical strategy of intubation, surfactant administration, and extubation to continuous positive airway pressure and the effect of continuous positive airway pressure on outcomes and surfactant use in preterm infants are also reviewed. (12/13)

SURVEILLANCE OF PEDIATRIC HIV INFECTION

Committee on Pediatric AIDS

ABSTRACT. Pediatric human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) surveillance should expand to include perinatal HIV exposure and HIV infection as well as AIDS to delineate

completely the extent and impact of HIV infection on children and families, accurately assess the resources necessary to provide services to this population, evaluate the efficacy of public health recommendations, and determine any potential long-term consequences of interventions to prevent perinatal transmission to children ultimately determined to be uninfected as well as for those who become infected. Ensuring the confidentiality of information collected in the process of surveillance is critical. In addition, expansion of surveillance must not compromise the established, ongoing surveillance system for pediatric AIDS. An expanded pediatric HIV surveillance program provides an important counterpart to existing American Academy of Pediatrics and American College of Obstetricians and Gynecologists recommendations for HIV counseling and testing in the prenatal setting. (2/98, reaffirmed 2/02, 1/06, 1/11)

THE TEEN DRIVER

Committee on Injury, Violence, and Poison Prevention and Committee on Adolescence

ABSTRACT. Motor vehicle–related injuries to adolescents continue to be of paramount importance to society. Since the original policy statement on the teenaged driver was published in 1996, there have been substantial changes in many state laws and much new research on this topic. There is a need to provide pediatricians with up-to-date information and materials to facilitate appropriate counseling and anticipatory guidance. This statement describes why teenagers are at greater risk of motor vehicle–related injuries, suggests topics suitable for office-based counseling, describes innovative programs, and proposes preventive interventions for pediatricians, parents, legislators, educators, and other child advocates. (12/06, reaffirmed 6/10)

TESTING FOR DRUGS OF ABUSE IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Sharon Levy, MD, MPH, FAAP; Lorena M. Siqueira, MD, MSPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Drug testing is often used as part of an assessment for substance use in children and adolescents. However, the indications for drug testing and guidance on how to use this procedure effectively are not clear. The complexity and invasiveness of the procedure and limitations to the information derived from drug testing all affect its utility. The objective of this clinical report is to provide guidance to pediatricians and other clinicians on the efficacy and efficient use of drug testing on the basis of a review of the nascent scientific literature, policy guidelines, and published clinical recommendations. (5/14)

See full text on page 1005.

TOBACCO, ALCOHOL, AND OTHER DRUGS: THE ROLE OF THE PEDIATRICIAN IN PREVENTION, IDENTIFICATION, AND MANAGEMENT OF SUBSTANCE ABUSE (CLINICAL REPORT)

John W. Kulig, MD, MPH, and Committee on Substance Abuse

ABSTRACT. Substance abuse remains a major public health concern, and pediatricians are uniquely positioned to assist their patients and families with its prevention, detection, and treatment. The American Academy of

Pediatrics has highlighted the importance of such issues in a variety of ways, including its guidelines for preventive services. The harmful consequences of tobacco, alcohol, and other drug use are a concern of medical professionals who care for infants, children, adolescents, and young adults. Thus, pediatricians should include discussion of substance abuse as a part of routine health care, starting with the prenatal visit, and as part of ongoing anticipatory guidance. Knowledge of the nature and extent of the consequences of tobacco, alcohol, and other drug use as well as the physical, psychological, and social consequences is essential for pediatricians. Pediatricians should incorporate substance-abuse prevention into daily practice, acquire the skills necessary to identify young people at risk of substance abuse, and provide or facilitate assessment, intervention, and treatment as necessary. (3/05, reaffirmed 3/13)

TOBACCO AS A SUBSTANCE OF ABUSE (TECHNICAL REPORT)

Tammy H. Sims, MD, MS, and Committee on Substance Abuse

ABSTRACT. Tobacco use is the leading preventable cause of morbidity and death in the United States. Because 80% to 90% of adult smokers began during adolescence, and two thirds became regular, daily smokers before they reached 19 years of age, tobacco use may be viewed as a pediatric disease. Every year in the United States, approximately 1.4 million children younger than 18 years start smoking, and many of them will die prematurely from a smoking-related disease. Moreover, there is recent evidence that adolescents report symptoms of tobacco dependence early in the smoking process, even before becoming daily smokers. The prevalence of tobacco use is higher among teenagers and young adults than among older adult populations. The critical role of pediatricians in helping to reduce tobacco use and addiction and secondhand tobacco-smoke exposure in the pediatric population includes education and prevention, screening and detection, and treatment and referral. (10/09)

TOBACCO USE: A PEDIATRIC DISEASE

Committee on Environmental Health, Committee on Substance Abuse, Committee on Adolescence, and Committee on Native American Child Health

ABSTRACT. Tobacco use and secondhand tobacco-smoke (SHS) exposure are major national and international health concerns. Pediatricians and other clinicians who care for children are uniquely positioned to assist patients and families with tobacco-use prevention and treatment. Understanding the nature and extent of tobacco use and SHS exposure is an essential first step toward the goal of eliminating tobacco use and its consequences in the pediatric population. The next steps include counseling patients and family members to avoid SHS exposures or cease tobacco use; advocacy for policies that protect children from SHS exposure; and elimination of tobacco use in the media, public places, and homes. Three overarching principles of this policy can be identified: (1) there is no safe way to use tobacco; (2) there is no safe level or duration of exposure to SHS; and (3) the financial and political power of individuals, organizations, and government should be

used to support tobacco control. Pediatricians are advised not to smoke or use tobacco; to make their homes, cars, and workplaces tobacco free; to consider tobacco control when making personal and professional decisions; to support and advocate for comprehensive tobacco control; and to advise parents and patients not to start using tobacco or to quit if they are already using tobacco. Prohibiting both tobacco advertising and the use of tobacco products in the media is recommended. Recommendations for eliminating SHS exposure and reducing tobacco use include attaining universal (1) smoke-free home, car, school, work, and play environments, both inside and outside, (2) treatment of tobacco use and dependence through employer, insurance, state, and federal supports, (3) implementation and enforcement of evidence-based tobacco-control measures in local, state, national, and international jurisdictions, and (4) financial and systems support for training in and research of effective ways to prevent and treat tobacco use and SHS exposure. Pediatricians, their staff and colleagues, and the American Academy of Pediatrics have key responsibilities in tobacco control to promote the health of children, adolescents, and young adults. (10/09, reaffirmed 5/13)

TOWARD TRANSPARENT CLINICAL POLICIES

Steering Committee on Quality Improvement and Management

ABSTRACT. Clinical policies of professional societies such as the American Academy of Pediatrics are valued highly, not only by clinicians who provide direct health care to children but also by many others who rely on the professional expertise of these organizations, including parents, employers, insurers, and legislators. The utility of a policy depends, in large part, on the degree to which its purpose and basis are clear to policy users, an attribute known as the policy's transparency. This statement describes the critical importance and special value of transparency in clinical policies, guidelines, and recommendations; helps identify obstacles to achieving transparency; and suggests several approaches to overcome these obstacles. (3/08, reaffirmed 2/14)

TRAMPOLINE SAFETY IN CHILDHOOD AND ADOLESCENCE

Council on Sports Medicine and Fitness

ABSTRACT. Despite previous recommendations from the American Academy of Pediatrics discouraging home use of trampolines, recreational use of trampolines in the home setting continues to be a popular activity among children and adolescents. This policy statement is an update to previous statements, reflecting the current literature on prevalence, patterns, and mechanisms of trampoline-related injuries. Most trampoline injuries occur with multiple simultaneous users on the mat. Cervical spine injuries often occur with falls off the trampoline or with attempts at somersaults or flips. Studies on the efficacy of trampoline safety measures are reviewed, and although there is a paucity of data, current implementation of safety measures have not appeared to mitigate risk substantially. Therefore, the home use of trampolines is strongly discouraged. The role of trampoline as a competitive sport and in structured training settings is reviewed,

and recommendations for enhancing safety in these environments are made. (9/12)

THE TRANSFER OF DRUGS AND THERAPEUTICS INTO HUMAN BREAST MILK: AN UPDATE ON SELECTED TOPICS (CLINICAL REPORT)

Hari Cheryl Sachs, MD, FAAP, and Committee on Drugs

ABSTRACT. Many mothers are inappropriately advised to discontinue breastfeeding or avoid taking essential medications because of fears of adverse effects on their infants. This cautious approach may be unnecessary in many cases, because only a small proportion of medications are contraindicated in breastfeeding mothers or associated with adverse effects on their infants. Information to inform physicians about the extent of excretion for a particular drug into human milk is needed but may not be available. Previous statements on this topic from the American Academy of Pediatrics provided physicians with data concerning the known excretion of specific medications into breast milk. More current and comprehensive information is now available on the Internet, as well as an application for mobile devices, at LactMed (<http://toxnet.nlm.nih.gov>). Therefore, with the exception of radioactive compounds requiring temporary cessation of breastfeeding, the reader will be referred to LactMed to obtain the most current data on an individual medication. This report discusses several topics of interest surrounding lactation, such as the use of psychotropic therapies, drugs to treat substance abuse, narcotics, galactagogues, and herbal products, as well as immunization of breastfeeding women. A discussion regarding the global implications of maternal medications and lactation in the developing world is beyond the scope of this report. The World Health Organization offers several programs and resources that address the importance of breastfeeding (see <http://www.who.int/topics/breastfeeding/en/>). (8/13)

TRANSITIONING HIV-INFECTED YOUTH INTO ADULT HEALTH CARE

Committee on Pediatric AIDS

ABSTRACT. With advances in antiretroviral therapy, most HIV-infected children survive into adulthood. Optimal health care for these youth includes a formal plan for the transition of care from primary and/or subspecialty pediatric/adolescent/family medicine health care providers (medical home) to adult health care provider(s). Successful transition involves the early engagement and participation of the youth and his or her family with the pediatric medical home and adult health care teams in developing a formal plan. Referring providers should have a written policy for the transfer of HIV-infected youth to adult care, which will guide in the development of an individualized plan for each youth. The plan should be introduced to the youth in early adolescence and modified as the youth approaches transition. Assessment of developmental milestones is important to define the readiness of the youth in assuming responsibility for his or her own care before initiating the transfer. Communication among all providers is essential and should include both personal contact and a written medical summary. Progress toward the transition should be tracked and, once completed, should be documented and assessed. (6/13)

TRANSPORTING CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Committee on Injury and Poison Prevention

ABSTRACT. Children with special health care needs should have access to proper resources for safe transportation. This statement reviews important considerations for transporting children with special health care needs and provides current guidelines for the protection of children with specific health care needs, including those with a tracheostomy, a spica cast, challenging behaviors, or muscle tone abnormalities as well as those transported in wheelchairs. (10/99, reaffirmed 1/03, 1/06, 3/13)

THE TREATMENT OF NEUROLOGICALLY IMPAIRED CHILDREN USING PATTERNING

Committee on Children With Disabilities

ABSTRACT. This statement reviews patterning as a treatment for children with neurologic impairments. This treatment is based on an outmoded and oversimplified theory of brain development. Current information does not support the claims of proponents that this treatment is efficacious, and its use continues to be unwarranted. (11/99, reaffirmed 11/02, 1/06, 8/10, 4/14)

ULTRAVIOLET RADIATION: A HAZARD TO CHILDREN AND ADOLESCENTS

Council on Environmental Health and Section on Dermatology

ABSTRACT. Ultraviolet radiation (UVR) causes the 3 major forms of skin cancer: basal cell carcinoma; squamous cell carcinoma; and cutaneous malignant melanoma. Public awareness of the risk is not optimal, overall compliance with sun protection is inconsistent, and melanoma rates continue to rise. The risk of skin cancer increases when people overexpose themselves to sun and intentionally expose themselves to artificial sources of UVR. Yet, people continue to sunburn, and teenagers and adults alike remain frequent visitors to tanning parlors. Pediatricians should provide advice about UVR exposure during health-supervision visits and at other relevant times. Advice includes avoiding sunburning, wearing clothing and hats, timing activities (when possible) before or after periods of peak sun exposure, wearing protective sunglasses, and applying and reapplying sunscreen. Advice should be framed in the context of promoting outdoor physical activity. Adolescents should be strongly discouraged from visiting tanning parlors. Sun exposure and vitamin D status are intertwined. Cutaneous vitamin D production requires sunlight exposure, and many factors, such as skin pigmentation, season, and time of day, complicate efficiency of cutaneous vitamin D production that results from sun exposure. Adequate vitamin D is needed for bone health. Accumulating information suggests a beneficial influence of vitamin D on many health conditions. Although vitamin D is available through the diet, supplements, and incidental sun exposure, many children have low vitamin D concentrations. Ensuring vitamin D adequacy while promoting sun-protection strategies will require renewed attention to children's use of dietary and supplemental vitamin D. (2/11)

ULTRAVIOLET RADIATION: A HAZARD TO CHILDREN AND ADOLESCENTS (TECHNICAL REPORT)

Sophie J. Balk, MD, Council on Environmental Health, and Section on Dermatology

ABSTRACT. Sunlight sustains life on earth. Sunlight is essential for vitamin D synthesis in the skin. The sun's ultraviolet rays can be hazardous, however, because excessive exposure causes skin cancer and other adverse health effects. Skin cancer is a major public health problem; more than 2 million new cases are diagnosed in the United States each year. Ultraviolet radiation (UVR) causes the 3 major forms of skin cancer: basal cell carcinoma; squamous cell carcinoma; and cutaneous malignant melanoma. Exposure to UVR from sunlight and artificial sources early in life elevates the risk of developing skin cancer. Approximately 25% of sun exposure occurs before 18 years of age. The risk of skin cancer is increased when people overexpose themselves to sun and intentionally expose themselves to artificial sources of UVR. Public awareness of the risk is not optimal, compliance with sun protection is inconsistent, and skin-cancer rates continue to rise in all age groups including the younger population. People continue to sunburn, and teenagers and adults are frequent visitors to tanning parlors. Sun exposure and vitamin D status are intertwined. Adequate vitamin D is needed for bone health in children and adults. In addition, there is accumulating information suggesting a beneficial influence of vitamin D on various health conditions. Cutaneous vitamin D production requires sunlight, and many factors complicate the efficiency of vitamin D production that results from sunlight exposure. Ensuring vitamin D adequacy while promoting sun-protection strategies, therefore, requires renewed attention to evaluating the adequacy of dietary and supplemental vitamin D. Daily intake of 400 IU of vitamin D will prevent vitamin D deficiency rickets in infants. The vitamin D supplementation amounts necessary to support optimal health in older children and adolescents are less clear. This report updates information on the relationship of sun exposure to skin cancer and other adverse health effects, the relationship of exposure to artificial sources of UVR and skin cancer, sun-protection methods, vitamin D, community skin-cancer-prevention efforts, and the pediatrician's role in preventing skin cancer. In addition to pediatricians' efforts, a sustained public health effort is needed to change attitudes and behaviors regarding UVR exposure. (3/11)

UNDERINSURANCE OF ADOLESCENTS: RECOMMENDATIONS FOR IMPROVED COVERAGE OF PREVENTIVE, REPRODUCTIVE, AND BEHAVIORAL HEALTH CARE SERVICES

Committee on Adolescence and Committee on Child Health Financing

ABSTRACT. The purpose of this policy statement is to address the serious underinsurance (ie, insurance that exists but is inadequate) problems affecting insured adolescents' access to needed preventive, reproductive, and behavioral health care. In addition, the statement addresses provider payment problems that disproportionately affect clinicians who care for adolescents.

Among adolescents with insurance, particularly private health insurance, coverage of needed services is often inadequate. Benefits are typically limited in scope and amount; certain diagnoses are often excluded; and cost-sharing requirements are often too high. As a result, underinsurance represents a substantial problem among adolescents and adversely affects their health and well-being.

In addition to underinsurance problems, payment problems in the form of inadequate payment, uncompensated care for confidential reproductive services, and the failure of insurers to recognize and pay for certain billing and diagnostic codes are widespread among both private and public insurers. Payment problems negatively affect clinicians' ability to offer needed services to adolescents, especially publicly insured adolescents. (12/08, reaffirmed 8/12)

UNDERSTANDING THE BEHAVIORAL AND EMOTIONAL CONSEQUENCES OF CHILD ABUSE (CLINICAL REPORT)

John Stirling, Jr, MD; Committee on Child Abuse and Neglect; and Section on Adoption and Foster Care (joint with Lisa Amaya-Jackson, MD, MPH, American Academy of Child and Adolescent Psychiatry, and National Center for Child Traumatic Stress)

ABSTRACT. Children who have suffered early abuse or neglect may later present with significant behavior problems including emotional instability, depression, and a tendency to be aggressive or violent with others. Troublesome behaviors may persist long after the abusive or neglectful environment has changed or the child has been in foster care placement. Neurobiological research has shown that early abuse results in an altered physiological response to stressful stimuli, a response that deleteriously affects the child's subsequent socialization. Pediatricians can assist caregivers by helping them recognize the abused or neglected child's altered responses, formulate more effective coping strategies, and mobilize available community resources. (9/08, reaffirmed 8/12)

UPDATE OF NEWBORN SCREENING AND THERAPY FOR CONGENITAL HYPOTHYROIDISM (CLINICAL REPORT)

Susan R. Rose, MD; Section on Endocrinology; and Committee on Genetics (joint with American Thyroid Association; Rosalind S. Brown, MD; and Lawson Wilkins Pediatric Endocrine Society)

ABSTRACT. Unrecognized congenital hypothyroidism leads to mental retardation. Newborn screening and thyroid therapy started within 2 weeks of age can normalize cognitive development. The primary thyroid-stimulating hormone screening has become standard in many parts of the world. However, newborn thyroid screening is not yet universal in some countries. Initial dosage of 10 to 15 µg/kg levothyroxine is recommended. The goals of thyroid hormone therapy should be to maintain frequent evaluations of total thyroxine or free thyroxine in the upper half of the reference range during the first 3 years of life and to normalize the serum thyroid-stimulating hormone concentration to ensure optimal thyroid hormone dosage and compliance.

Improvements in screening and therapy have led to improved developmental outcomes in adults with congenital hypothyroidism who are now in their 20s and 30s. Thyroid hormone regimens used today are more aggressive in targeting early correction of thyroid-stimulating hormone than were those used 20 or even 10 years ago. Thus, newborn infants with congenital hypothyroidism today may have an even better intellectual and neurologic prognosis. Efforts are ongoing to establish the optimal therapy that leads to maximum potential for normal development for infants with congenital hypothyroidism.

Remaining controversy centers on infants whose abnormality in neonatal thyroid function is transient or mild and on optimal care of very low birth weight or preterm infants. Of note, thyroid-stimulating hormone is not elevated in central hypothyroidism. An algorithm is proposed for diagnosis and management.

Physicians must not relinquish their clinical judgment and experience in the face of normal newborn thyroid test results. Hypothyroidism can be acquired after the newborn screening. When clinical symptoms and signs suggest hypothyroidism, regardless of newborn screening results, serum free thyroxine and thyroid-stimulating hormone determinations should be performed. (6/06, reaffirmed 12/11)

UPDATED GUIDANCE FOR PALIVIZUMAB PROPHYLAXIS AMONG INFANTS AND YOUNG CHILDREN AT INCREASED RISK OF HOSPITALIZATION FOR RESPIRATORY SYNCYTIAL VIRUS INFECTION



Committee on Infectious Diseases and Bronchiolitis Guidelines Committee

ABSTRACT. Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 Red Book. (7/14)

See full text on page 1017.

UPDATED GUIDANCE FOR PALIVIZUMAB PROPHYLAXIS AMONG INFANTS AND YOUNG CHILDREN AT INCREASED RISK OF HOSPITALIZATION FOR RESPIRATORY SYNCYTIAL VIRUS INFECTION (TECHNICAL REPORT)

Committee on Infectious Diseases and Bronchiolitis

Guidelines Committee

ABSTRACT. Guidance from the American Academy of Pediatrics (AAP) for the use of palivizumab prophylaxis against respiratory syncytial virus (RSV) was first published in a policy statement in 1998. Guidance initially was based on the result from a single randomized, placebo-controlled clinical trial conducted in 1996–1997 describing an overall reduction in RSV hospitalization rate from 10.6% among placebo recipients to 4.8% among children who received prophylaxis. The results of a second randomized, placebo-controlled trial of children with hemodynamically significant heart disease were published in 2003 and revealed a reduction in RSV hospitalization rate from 9.7% in control subjects to 5.3% among prophylaxis recipients. Because no additional controlled trials regarding efficacy were published, AAP guidance has been updated periodically to reflect the most recent literature regarding children at greatest risk of severe disease. Since the last update in 2012, new data have become available regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effects of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, and the effect of prophylaxis on wheezing and palivizumab-resistant RSV isolates. These data enable further refinement of AAP guidance to most clearly focus on those children at greatest risk. (7/14)

See full text on page 1027.

UPDATED RECOMMENDATIONS ON THE USE OF MENINGOCOCCAL VACCINES

Committee on Infectious Diseases

ABSTRACT. Since the last policy statement from the American Academy of Pediatrics (AAP) concerning meningococcal vaccine was published in 2011, 2 meningococcal conjugate vaccines have been licensed for use in infants (Hib-MenCY-TT and MenACWY-CRM). The Centers for Disease Control and Prevention (CDC) has published new recommendations, "Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices," which have been endorsed by the AAP. However, the CDC recommendations were published before licensure of MenACWY-CRM for infant use. This policy statement updates the AAP recommendations for use of meningococcal vaccines in children and adolescents. A more comprehensive review of background and technical information can be found in the CDC publication. (7/14)

See full text on page 1049.

THE USE AND MISUSE OF FRUIT JUICE IN PEDIATRICS

Committee on Nutrition

ABSTRACT. Historically, fruit juice was recommended by pediatricians as a source of vitamin C and an extra source of water for healthy infants and young children as their

diets expanded to include solid foods with higher renal solute. Fruit juice is marketed as a healthy, natural source of vitamins and, in some instances, calcium. Because juice tastes good, children readily accept it. Although juice consumption has some benefits, it also has potential detrimental effects. Pediatricians need to be knowledgeable about juice to inform parents and patients on its appropriate uses. (5/01, reaffirmed 10/06, 8/13)

USE OF CHAPERONES DURING THE PHYSICAL EXAMINATION OF THE PEDIATRIC PATIENT

Committee on Practice and Ambulatory Medicine

ABSTRACT. Physicians should always communicate the scope and nature of the physical examination to be performed to the pediatric patient and his or her parent. This statement addresses the use of chaperones and issues of patient comfort, confidentiality, and privacy. The use of a chaperone should be a shared decision between the patient and physician. In some states, the use of a chaperone is mandated by state regulations. (4/11)

USE OF CODEINE- AND DEXTROMETHORPHAN-CONTAINING COUGH REMEDIES IN CHILDREN

Committee on Drugs

ABSTRACT. Numerous prescription and nonprescription medications are currently available for suppression of cough, a common symptom in children. Because adverse effects and overdosage associated with the administration of cough and cold preparations in children have been reported, education of patients and parents about the lack of proven antitussive effects and the potential risks of these products is needed. (6/97, reaffirmed 5/00, 6/03, 10/06)

THE USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE IN PEDIATRICS (CLINICAL REPORT)

Kathi J. Kemper, MD, MPH; Sunita Vohra, MD; Richard Walls, MD, PhD; Task Force on Complementary and Alternative Medicine; and Provisional Section on Complementary, Holistic, and Integrative Medicine

ABSTRACT. The American Academy of Pediatrics is dedicated to optimizing the well-being of children and advancing family-centered health care. Related to these goals, the American Academy of Pediatrics recognizes the increasing use of complementary and alternative medicine in children and, as a result, the need to provide information and support for pediatricians. From 2000 to 2002, the American Academy of Pediatrics convened and charged the Task Force on Complementary and Alternative Medicine to address issues related to the use of complementary and alternative medicine in children and to develop resources to educate physicians, patients, and families. One of these resources is this report describing complementary and alternative medicine services, current levels of utilization and financial expenditures, and associated legal and ethical considerations. The subject of complementary and alternative medicine is large and diverse, and consequently, an in-depth discussion of each method of complementary and alternative medicine is beyond the scope of this report. Instead, this report will define terms; describe epidemiology; outline common types of complementary and alternative medicine therapies; review medicolegal, ethical, and research implica-

tions; review education and training for complementary and alternative medicine providers; provide resources for learning more about complementary and alternative medicine; and suggest communication strategies to use when discussing complementary and alternative medicine with patients and families. (12/08, reaffirmed 10/12, 1/13)

USE OF INHALED NITRIC OXIDE

Committee on Fetus and Newborn

ABSTRACT. Approval of inhaled nitric oxide by the US Food and Drug Administration for hypoxic respiratory failure of the term and near-term newborn provides an important new therapy for this serious condition. This statement addresses the conditions under which inhaled nitric oxide should be administered to the neonate with hypoxic respiratory failure. (8/00, reaffirmed 4/03, 12/09)

USE OF INHALED NITRIC OXIDE IN PRETERM INFANTS (CLINICAL REPORT)

Praveen Kumar, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Nitric oxide, an important signaling molecule with multiple regulatory effects throughout the body, is an important tool for the treatment of full-term and late-preterm infants with persistent pulmonary hypertension of the newborn and hypoxemic respiratory failure. Several randomized controlled trials have evaluated its role in the management of preterm infants ≤ 34 weeks' gestational age with varying results. The purpose of this clinical report is to summarize the existing evidence for the use of inhaled nitric oxide in preterm infants and provide guidance regarding its use in this population. (12/13)

USE OF PERFORMANCE-ENHANCING SUBSTANCES

Committee on Sports Medicine and Fitness

ABSTRACT. Performance-enhancing substances include dietary supplements, prescription medications, and illicit drugs. Virtually no data are available on the efficacy and safety in children and adolescents of widely used performance-enhancing substances. This statement is intended to provide a generalized but functional definition of performance-enhancing substances. The American Academy of Pediatrics strongly condemns the use of performance-enhancing substances and vigorously endorses efforts to eliminate their use among children and adolescents. (4/05, reaffirmed 5/08)

USE OF SOY PROTEIN-BASED FORMULAS IN INFANT FEEDING (CLINICAL REPORT)

Jatinder Bhatia, MD; Frank Greer, MD; and Committee on Nutrition

ABSTRACT. Soy protein-based formulas have been available for almost 100 years. Since the first use of soy formula as a milk substitute for an infant unable to tolerate a cow milk protein-based formula, the formulation has changed to the current soy protein isolate. Despite very limited indications for its use, soy protein-based formulas in the United States may account for nearly 25% of the formula market. This report reviews the limited indications and contraindications of soy formulas. It will also review the potential harmful effects of soy protein-based formulas and the phytoestrogens contained in these formulas. (5/08)

THE USE OF SYSTEMIC AND TOPICAL FLUOROQUINOLONES (CLINICAL REPORT)

John S. Bradley, MD; Mary Anne Jackson, MD; and Committee on Infectious Diseases

ABSTRACT. Appropriate prescribing practices for fluoroquinolones are essential as evolving resistance patterns are considered, additional treatment indications are identified, and the toxicity profile of fluoroquinolones in children becomes better defined. Earlier recommendations for systemic therapy remain; expanded uses of fluoroquinolones for the treatment of certain infections are outlined in this report. Although fluoroquinolones are reasonably safe in children, clinicians should be aware of the specific adverse reactions. Use of fluoroquinolones in children should continue to be limited to treatment of infections for which no safe and effective alternative exists. (9/11)

USES OF DRUGS NOT DESCRIBED IN THE PACKAGE INSERT (OFF-LABEL USES)

Committee on Drugs

ABSTRACT. New regulatory initiatives have been designed to ensure that new drugs and biologicals include adequate pediatric labeling for the claimed indications at the time of, or soon after, approval. However, because such labeling may not immediately be available, off-label use (or use that is not included in the approved label) of therapeutic agents is likely to remain common in the practice of pediatrics. This policy statement was written to address questions practitioners have regarding off-label use. The purpose of off-label use is to benefit the individual patient. Practitioners may use their professional judgment to determine these uses. Practitioners should understand that the Food and Drug Administration does not regulate off-label use. (7/02, reaffirmed 10/05)

VENTRICULAR FIBRILLATION AND THE USE OF AUTOMATED EXTERNAL DEFIBRILLATORS ON CHILDREN

Committee on Pediatric Emergency Medicine and Section on Cardiology and Cardiac Surgery

ABSTRACT. The use of automated external defibrillators (AEDs) has been advocated in recent years as one part of the chain of survival to improve outcomes for adult cardiac arrest victims. When AEDs first entered the market, they had not been tested for pediatric usage and rhythm interpretation. In addition, the presumption was that children do not experience ventricular fibrillation, so they would not benefit from the use of AEDs. Recent literature has shown that children do experience ventricular fibrillation, which has a better outcome than do other cardiac arrest rhythms. At the same time, the arrhythmia software on AEDs has become more extensive and validated for children, and attenuation devices have become available to downregulate the energy delivered by AEDs to allow their use on children. Pediatricians are now being asked whether AED programs should be implemented, and where they are being implemented, pediatricians are being asked to provide guidance on the use of them on children. As AED programs expand, pediatricians must advocate on behalf of children so that their needs are accounted for. For pediatricians to be able to provide guidance and ensure that children are included in AED programs, it is important for pediatricians to know how

AEDs work, be up-to-date on the literature regarding pediatric fibrillation and energy delivery, and understand the role of AEDs as life-saving interventions for children. (11/07, reaffirmed 6/11, 7/14)

WHEN IS LACK OF SUPERVISION NEGLECT? (CLINICAL REPORT)

Kent P. Hymel, MD, and Committee on Child Abuse and Neglect
ABSTRACT. Occasionally, pediatricians become aware of children who are inadequately supervised. More frequently, pediatricians treat children for traumatic injuries or ingestions that they suspect could have been prevented with better supervision. This clinical report contains guidance for pediatricians considering a referral to a child protective services agency on the basis of suspicion of supervisory neglect. (9/06)

WIC PROGRAM

Provisional Section on Breastfeeding

ABSTRACT. This policy statement highlights the important collaboration between pediatricians and local Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) programs to ensure that infants and children receive high-quality, cost-effective health care and nutrition services. Specific recommendations are provided for pediatricians and WIC personnel to help children and their families receive optimum services through a medical home. (11/01)

WITHHOLDING OR TERMINATION OF RESUSCITATION IN PEDIATRIC OUT-OF-HOSPITAL TRAUMATIC CARDIOPULMONARY ARREST

*Committee on Pediatric Emergency Medicine (joint with
American College of Surgeons Committee on Trauma and
National Association of EMS Physicians)*

ABSTRACT. This multiorganizational literature review was undertaken to provide an evidence base for determining whether recommendations for out-of-hospital termination of resuscitation could be made for children who are victims of traumatic cardiopulmonary arrest. Although there is increasing acceptance of out-of-hospital termination of resuscitation for adult traumatic cardiopulmonary arrest when there is no expectation of a good outcome, children are routinely excluded from state termination-of-resuscitation protocols. The decision to withhold resuscitative efforts in a child under specific circumstances (decapitation or dependent lividity, rigor

mortis, etc) is reasonable. If there is any doubt as to the circumstances or timing of the traumatic cardiopulmonary arrest, under the current status of limiting termination of resuscitation in the field to persons older than 18 years in most states, resuscitation should be initiated and continued until arrival to the appropriate facility. If the patient has arrested, resuscitation has already exceeded 30 minutes, and the nearest facility is more than 30 minutes away, involvement of parents and family of these children in the decision-making process with assistance and guidance from medical professionals should be considered as part of an emphasis on family-centered care because the evidence suggests that either death or a poor outcome is inevitable. (3/14)

See full text on page 1055.

YEAR 2007 POSITION STATEMENT: PRINCIPLES AND GUIDELINES FOR EARLY HEARING DETECTION AND INTERVENTION PROGRAMS:

Joint Committee on Infant Hearing

ABSTRACT. The Joint Committee on Infant Hearing (JCIH) endorses early detection of and intervention for infants with hearing loss. The goal of early hearing detection and intervention (EHDI) is to maximize linguistic competence and literacy development for children who are deaf or hard of hearing. Without appropriate opportunities to learn language, these children will fall behind their hearing peers in communication, cognition, reading, and social-emotional development. Such delays may result in lower educational and employment levels in adulthood. To maximize the outcome for infants who are deaf or hard of hearing, the hearing of all infants should be screened at no later than 1 month of age. Those who do not pass screening should have a comprehensive audiological evaluation at no later than 3 months of age. Infants with confirmed hearing loss should receive appropriate intervention at no later than 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children. Regardless of previous hearing-screening outcomes, all infants with or without risk factors should receive ongoing surveillance of communicative development beginning at 2 months of age during well-child visits in the medical home. EHDI systems should guarantee seamless transitions for infants and their families through this process. (10/07)

SECTION 6

Endorsed Policies

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*The American Academy of Pediatrics endorses
and accepts as its policy the following
documents from other organizations.*

AMERICAN ACADEMY OF PEDIATRICS

Endorsed Policies

ADVANCED PRACTICE REGISTERED NURSE: ROLE, PREPARATION, AND SCOPE OF PRACTICE

National Association of Neonatal Nurses

In recent years, the National Association of Neonatal Nurses (NANN) and the National Association of Neonatal Nurse Practitioners (NANNP) have developed several policy statements on neonatal advanced practice registered nurse (APRN) workforce, education, competency, fatigue, safety, and scope of practice. This position paper is a synthesis of previous efforts and discusses the role, preparation, and scope of practice of the neonatal APRN. (1/14)

APPROPRIATE MEDICAL CARE FOR THE SECONDARY SCHOOL-AGE ATHLETE COMMUNICATION

National Athletic Trainers' Association (2004)

APPROPRIATE USE CRITERIA FOR INITIAL TRANSTHORACIC ECHOCARDIOGRAPHY IN OUTPATIENT PEDIATRIC CARDIOLOGY

American College of Cardiology Appropriate Use Task Force

ABSTRACT. The American College of Cardiology (ACC) participated in a joint project with the American Society of Echocardiography, the Society of Pediatric Echocardiography, and several other subspecialty societies and organizations to establish and evaluate Appropriate Use Criteria (AUC) for the initial use of outpatient pediatric echocardiography. Assumptions for the AUC were identified, including the fact that all indications assumed a first-time transthoracic echocardiographic study in an outpatient setting for patients without previously known heart disease. The definitions for frequently used terminology in outpatient pediatric cardiology were established using published guidelines and standards and expert opinion. These AUC serve as a guide to help clinicians in the care of children with possible heart disease, specifically in terms of when a transthoracic echocardiogram is warranted as an initial diagnostic modality in the outpatient setting. They are also a useful tool for education and provide the infrastructure for future quality improvement initiatives as well as research in healthcare delivery, outcomes, and resource utilization.

To complete the AUC process, the writing group identified 113 indications based on common clinical scenarios and/or published clinical practice guidelines, and each indication was classified into 1 of 9 categories of common clinical presentations, including palpitations, syncope, chest pain, and murmur. A separate, independent rating panel evaluated each indication using a scoring scale of 1 to 9, thereby designating each indication as "Appropriate" (median score 7 to 9), "May Be Appropriate" (median score 4 to 6), or "Rarely Appropriate" (median score 1 to 3). Fifty-three indications were identified as Appropriate, 28 as May Be Appropriate, and 32 as Rarely Appropriate. (11/14)

BEST PRACTICE FOR INFANT SURGERY: A POSITION STATEMENT FROM THE AMERICAN PEDIATRIC SURGICAL ASSOCIATION

American Pediatric Surgical Association (9/08)

CARDIOVASCULAR RISK REDUCTION IN HIGH-RISK PEDIATRIC POPULATIONS

American Heart Association

ABSTRACT. Although for most children the process of atherosclerosis is subclinical, dramatically accelerated atherosclerosis occurs in some pediatric disease states, with clinical coronary events occurring in childhood and very early adult life. As with most scientific statements about children and the future risk for cardiovascular disease, there are no randomized trials documenting the effects of risk reduction on hard clinical outcomes. A growing body of literature, however, identifies the importance of premature cardiovascular disease in the course of certain pediatric diagnoses and addresses the response to risk factor reduction. For this scientific statement, a panel of experts reviewed what is known about very premature cardiovascular disease in 8 high-risk pediatric diagnoses and, from the science base, developed practical recommendations for management of cardiovascular risk. (*Circulation*. 2006;114:000-000.) (12/06)

A COMPREHENSIVE IMMUNIZATION STRATEGY TO ELIMINATE TRANSMISSION OF HEPATITIS B VIRUS INFECTION IN THE UNITED STATES

Advisory Committee on Immunization Practices and Centers for Disease Control and Prevention

SUMMARY. This report is the first of a two-part statement from the Advisory Committee on Immunization Practices (ACIP) that updates the strategy to eliminate hepatitis B virus (HBV) transmission in the United States. The report provides updated recommendations to improve prevention of perinatal and early childhood HBV transmission, including implementation of universal infant vaccination beginning at birth, and to increase vaccine coverage among previously unvaccinated children and adolescents. Strategies to enhance implementation of the recommendations include 1) establishing standing orders for administration of hepatitis B vaccination beginning at birth; 2) instituting delivery hospital policies and procedures and case management programs to improve identification of and administration of immunoprophylaxis to infants born to mothers who are hepatitis B surface antigen (HBsAg) positive and to mothers with unknown HBsAg status at the time of delivery; and 3) implementing vaccination record reviews for all children aged 11-12 years and children and adolescents aged <19 years who were born in countries with intermediate and high levels of HBV endemicity, adopting hepatitis B vaccine requirements for school entry, and integrating hepatitis B vaccination services into settings that serve adolescents. The second part of the ACIP statement, which will include

updated recommendations and strategies to increase hepatitis B vaccination of adults, will be published separately. (7/06)

CONSENSUS STATEMENT: DEFINITIONS FOR CONSISTENT EMERGENCY DEPARTMENT METRICS

American Academy of Emergency Medicine, American Association of Critical Care Nurses, American College of Emergency Physicians, Association of periOperative Registered Nurses, Emergency Department Practice Management Association, Emergency Nurses Association, and National Association of EMS Physicians (2/10)

CONSENSUS STATEMENT ON MANAGEMENT OF INTERSEX DISORDERS

International Consensus Conference on Intersex (Lawson Wilkins Pediatric Endocrine Society and European Society for Paediatric Endocrinology)

INTRODUCTION. The birth of an intersex child prompts a long-term management strategy that involves myriad professionals working with the family. There has been progress in diagnosis, surgical techniques, understanding psychosocial issues, and recognizing and accepting the place of patient advocacy. The Lawson Wilkins Pediatric Endocrine Society and the European Society for Paediatric Endocrinology considered it timely to review the management of intersex disorders from a broad perspective, review data on longer-term outcome, and formulate proposals for future studies. The methodology comprised establishing a number of working groups, the membership of which was drawn from 50 international experts in the field. The groups prepared previous written responses to a defined set of questions resulting from evidence-based review of the literature. At a subsequent gathering of participants, a framework for a consensus document was agreed. This article constitutes its final form. (8/06)

DEFINING PEDIATRIC MALNUTRITION: A PARADIGM SHIFT TOWARD ETIOLOGY-RELATED DEFINITIONS

American Society for Parenteral and Enteral Nutrition

ABSTRACT. Lack of a uniform definition is responsible for underrecognition of the prevalence of malnutrition and its impact on outcomes in children. A pediatric malnutrition definitions workgroup reviewed existing pediatric age group English-language literature from 1955 to 2011, for relevant references related to 5 domains of the definition of *malnutrition* that were *a priori* identified: anthropometric parameters, growth, chronicity of malnutrition, etiology and pathogenesis, and developmental/ functional outcomes. Based on available evidence and an iterative process to arrive at multidisciplinary consensus in the group, these domains were included in the overall construct of a new definition. Pediatric malnutrition (undernutrition) is defined as an imbalance between nutrient requirements and intake that results in cumulative deficits of energy, protein, or micronutrients that may negatively affect growth, development, and other relevant outcomes. A summary of the literature is presented and a new classification scheme is proposed that incorporates chronicity, etiology, mechanisms of nutrient imbalance, severity of malnutrition, and its impact on outcomes. Based on its etiology, malnutrition is either *illness related* (secondary to

1 or more diseases/injury) or *non-illness related*, (caused by environmental/behavioral factors), or both. Future research must focus on the relationship between inflammation and illness-related malnutrition. We anticipate that the definition of malnutrition will continue to evolve with improved understanding of the processes that lead to and complicate the treatment of this condition. A uniform definition should permit future research to focus on the impact of pediatric malnutrition on functional outcomes and help solidify the scientific basis for evidence-based nutrition practices. (3/13)

DIABETES CARE FOR EMERGING ADULTS: RECOMMENDATIONS FOR TRANSITION FROM PEDIATRIC TO ADULT DIABETES CARE SYSTEMS

American Diabetes Association (11/11)

DIAGNOSIS, TREATMENT, AND LONG-TERM MANAGEMENT OF KAWASAKI DISEASE: A STATEMENT FOR HEALTH PROFESSIONALS

American Heart Association (12/04)

DIETARY RECOMMENDATIONS FOR CHILDREN AND ADOLESCENTS: A GUIDE FOR PRACTITIONERS

American Heart Association (9/05)

DIETARY REFERENCE INTAKES FOR CALCIUM AND VITAMIN D

Institute of Medicine (2011)

EMERGENCY EQUIPMENT AND SUPPLIES IN THE SCHOOL SETTING

National Association of School Nurses (1/12)

ENHANCING THE WORK OF THE HHS NATIONAL VACCINE PROGRAM IN GLOBAL IMMUNIZATIONS

National Vaccine Advisory Committee (9/13)

EVIDENCE REPORT: GENETIC AND METABOLIC TESTING ON CHILDREN WITH GLOBAL DEVELOPMENTAL DELAY

American Academy of Neurology and Child Neurology Society
ABSTRACT. *Objective.* To systematically review the evidence concerning the diagnostic yield of genetic and metabolic evaluation of children with global developmental delay or intellectual disability (GDD/ID).

Methods. Relevant literature was reviewed, abstracted, and classified according to the 4-tiered American Academy of Neurology classification of evidence scheme.

Results and Conclusions. In patients with GDD/ID, microarray testing is diagnostic on average in 7.8% (Class III), G-banded karyotyping is abnormal in at least 4% (Class II and III), and subtelomeric fluorescence in situ hybridization is positive in 3.5% (Class I, II, and III). Testing for X-linked ID genes has a yield of up to 42% in males with an appropriate family history (Class III). *FMR1* testing shows full expansion in at least 2% of patients with mild to moderate GDD/ID (Class II and III), and *MeCP2* testing is diagnostic in 1.5% of females with moderate to severe GDD/ID (Class III). Tests for metabolic disorders have a yield of up to 5%, and tests for congenital disorders of glycosylation and cerebral creatine disorders have yields of up to 2.8% (Class III). Several genetic and metabolic screening tests have been shown to have a better than 1%

diagnostic yield in selected populations of children with GDD/ID. These values should be among the many factors considered in planning the laboratory evaluation of such children. (9/11)

EVIDENCE-BASED GUIDELINE UPDATE: MEDICAL TREATMENT OF INFANTILE SPASMS

American Academy of Neurology and Child Neurology Society
ABSTRACT. Objective. To update the 2004 American Academy of Neurology/Child Neurology Society practice parameter on treatment of infantile spasms in children.

Methods. MEDLINE and EMBASE were searched from 2002 to 2011 and searches of reference lists of retrieved articles were performed. Sixty-eight articles were selected for detailed review; 26 were included in the analysis. Recommendations were based on a 4-tiered classification scheme combining pre-2002 evidence and more recent evidence.

Results. There is insufficient evidence to determine whether other forms of corticosteroids are as effective as adrenocorticotrophic hormone (ACTH) for short-term treatment of infantile spasms. However, low-dose ACTH is probably as effective as high-dose ACTH. ACTH is more effective than vigabatrin (VGB) for short-term treatment of children with infantile spasms (excluding those with tuberous sclerosis complex). There is insufficient evidence to show that other agents and combination therapy are effective for short-term treatment of infantile spasms. Short lag time to treatment leads to better long-term developmental outcome. Successful short-term treatment of cryptogenic infantile spasms with ACTH or prednisolone leads to better long-term developmental outcome than treatment with VGB.

Recommendations. Low-dose ACTH should be considered for treatment of infantile spasms. ACTH or VGB may be useful for short-term treatment of infantile spasms, with ACTH considered preferentially over VGB. Hormonal therapy (ACTH or prednisolone) may be considered for use in preference to VGB in infants with cryptogenic infantile spasms, to possibly improve developmental outcome. A shorter lag time to treatment of infantile spasms with either hormonal therapy or VGB possibly improves long-term developmental outcomes. (6/12)

EVIDENCE-BASED MANAGEMENT OF SICKLE CELL DISEASE: EXPERT PANEL REPORT, 2014

National Heart, Lung, and Blood Institute (2014)

EXECUTING JUVENILE OFFENDERS: A FUNDAMENTAL FAILURE OF SOCIETY

Society for Adolescent Medicine (10/04)

EXPEDITED PARTNER THERAPY FOR ADOLESCENTS DIAGNOSED WITH CHLAMYDIA OR GONORRHEA: A POSITION PAPER OF THE SOCIETY FOR ADOLESCENT MEDICINE

Society for Adolescent Medicine

ABSTRACT. Chlamydia and gonorrhea, the most frequently reported sexually transmitted infections (STIs), present substantial public health challenges among adolescents. Although these infections are easily treated with antibiotics, many adolescents are reinfected within 3–6 months, usually because their partners remain untreated.

The standard approaches to notifying and treating a partner of an STI-infected patient are patient referral, whereby the patient notifies his/her partners to seek care, and provider referral, whereby the provider or public health disease intervention specialist notifies the partner and directs him/her toward treatment. These methods rely on the accuracy of the disclosed partner information as well as other limitations, such as compliance and staffing resources. Another approach to partner notification is expedited partner therapy (EPT), treating sex partners without requiring a prior clinical evaluation. In randomized trials, EPT has reduced the rates of persistent or recurrent gonorrhea and chlamydia infection; however, its routine use is limited by concerns related to liability, cost, compliance, and missed opportunities for prevention counseling. The Society for Adolescent Medicine (SAM) recommends that providers who care for adolescents should do the following: use EPT as an option for STI care among chlamydia- or gonorrhea-infected heterosexual males and females who are unlikely or unable to otherwise receive treatment; through SAM and AAP chapters, collaborate with policy makers to remove EPT legal barriers and facilitate reimbursement; and collaborate with health departments for implementation assistance. (9/09)

EXPERT PANEL ON INTEGRATED GUIDELINES FOR CARDIOVASCULAR HEALTH AND RISK REDUCTION IN CHILDREN AND ADOLESCENTS: SUMMARY REPORT

National Heart, Lung and Blood Institute

INTRODUCTION (EXCERPT). Atherosclerotic cardiovascular disease (CVD) remains the leading cause of death in North Americans, but manifest disease in childhood and adolescence is rare. By contrast, risk factors and risk behaviors that accelerate the development of atherosclerosis begin in childhood, and there is increasing evidence that risk reduction delays progression toward clinical disease. In response, the former director of the National Heart, Lung, and Blood Institute (NHLBI), Dr Elizabeth Nabel, initiated development of cardiovascular health guidelines for pediatric care providers based on a formal evidence review of the science with an integrated format addressing all the major cardiovascular risk factors simultaneously. An expert panel was appointed to develop the guidelines in the fall of 2006. (3/12)

FOSTER CARE MENTAL HEALTH VALUES

American Academy of Child and Adolescent Psychiatry and Child Welfare League of America (2002)

GENERAL RECOMMENDATIONS ON IMMUNIZATION: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Advisory Committee on Immunization Practices

SUMMARY. This report is a revision of General Recommendations on Immunization and updates the 2002 statement by the Advisory Committee on Immunization Practices (ACIP) (CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. *MMWR* 2002;51[No. RR-2]). This report is intended to serve as a general reference on vaccines and immunization. The principal changes include 1) expansion of the discussion of vac-

cination spacing and timing; 2) an increased emphasis on the importance of injection technique/age/body mass in determining appropriate needle length; 3) expansion of the discussion of storage and handling of vaccines, with a table defining the appropriate storage temperature range for inactivated and live vaccines; 4) expansion of the discussion of altered immunocompetence, including new recommendations about use of live-attenuated vaccines with therapeutic monoclonal antibodies; and 5) minor changes to the recommendations about vaccination during pregnancy and vaccination of internationally adopted children, in accordance with new ACIP vaccine-specific recommendations for use of inactivated influenza vaccine and hepatitis B vaccine. The most recent ACIP recommendations for each specific vaccine should be consulted for comprehensive discussion. This report, ACIP recommendations for each vaccine, and other information about vaccination can be accessed at CDC's National Center for Immunization and Respiratory Diseases (proposed) (formerly known as the National Immunization Program) website at <http://www.cdc.gov/nip>. (12/06)

GENETIC BASIS FOR CONGENITAL HEART DEFECTS: CURRENT KNOWLEDGE

American Heart Association

ABSTRACT. The intent of this review is to provide the clinician with a summary of what is currently known about the contribution of genetics to the origin of congenital heart disease. Techniques are discussed to evaluate children with heart disease for genetic alterations. Many of these techniques are now available on a clinical basis. Information on the genetic and clinical evaluation of children with cardiac disease is presented, and several tables have been constructed to aid the clinician in the assessment of children with different types of heart disease. Genetic algorithms for cardiac defects have been constructed and are available in an appendix. It is anticipated that this summary will update a wide range of medical personnel, including pediatric cardiologists and pediatricians, adult cardiologists, internists, obstetricians, nurses, and thoracic surgeons, about the genetic aspects of congenital heart disease and will encourage an interdisciplinary approach to the child and adult with congenital heart disease. (*Circulation*. 2007;115:3015-3038.) (6/07)

GIFTS TO PHYSICIANS FROM INDUSTRY

American Medical Association (8/01)

GUIDELINES FOR FIELD TRIAGE OF INJURED PATIENTS *Centers for Disease Control and Prevention* (1/12)

GUIDELINES FOR REFERRAL OF CHILDREN AND ADOLESCENTS TO PEDIATRIC RHEUMATOLOGISTS

American College of Rheumatology (6/02, reaffirmed 5/07)

HELPING THE STUDENT WITH DIABETES SUCCEED: A GUIDE FOR SCHOOL PERSONNEL

National Diabetes Education Program (6/03)

IDENTIFYING AND RESPONDING TO DOMESTIC VIOLENCE: CONSENSUS RECOMMENDATIONS FOR CHILD AND ADOLESCENT HEALTH

Family Violence Prevention Fund (9/02)

IMPORTANCE AND IMPLEMENTATION OF TRAINING IN CARDIOPULMONARY RESUSCITATION AND AUTOMATED EXTERNAL DEFIBRILLATION IN SCHOOLS

American Heart Association Emergency Cardiovascular Care Committee; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Diseases in the Young; Council on Cardiovascular Nursing; Council on Clinical Cardiology; and Advocacy Coordinating Committee

ABSTRACT. In 2003, the International Liaison Committee on Resuscitation published a consensus document on education in resuscitation that strongly recommended that "...instruction in CPR [cardiopulmonary resuscitation] be incorporated as a standard part of the school curriculum." The next year the American Heart Association (AHA) recommended that schools "...establish a goal to train every teacher in CPR and first aid and train all students in CPR" as part of their preparation for a response to medical emergencies on campus.

Since that time, there has been an increased interest in legislation that would mandate that school curricula include training in CPR or CPR and automated external defibrillation. Laws or curriculum content standards in 36 states (as of the 2009–2010 school year) now encourage the inclusion of CPR training programs in school curricula. The language in those laws and standards varies greatly, ranging from a suggestion that students "recognize" the steps of CPR to a requirement for certification in CPR. Not surprisingly, then, implementation is not uniform among states, even those whose laws or standards encourage CPR training in schools in the strongest language. This statement recommends that training in CPR and familiarization with automated external defibrillators (AEDs) should be required elements of secondary school curricula and provides the rationale for implementation of CPR training, as well as guidance in overcoming barriers to implementation. (2/11)

INTER-ASSOCIATION CONSENSUS STATEMENT ON BEST PRACTICES FOR SPORTS MEDICINE MANAGEMENT FOR SECONDARY SCHOOLS AND COLLEGES

National Athletic Trainers Association, National Interscholastic Athletic Administrators Association, College Athletic Trainers' Society, National Federation of State High School Associations, American College Health Association, American Orthopaedic Society for Sports Medicine, National Collegiate Athletic Association, American Medical Society for Sports Medicine, National Association of Collegiate Directors of Athletics, and National Association of Intercollegiate Athletics (7/13)

LIGHTNING SAFETY FOR ATHLETICS AND RECREATION

National Athletic Trainers' Association

ABSTRACT. *Objective.* To educate athletic trainers and others about the dangers of lightning, provide lightning-safety guidelines, define safe structures and locations, and advocate prehospital care for lightning-strike victims. *Background.* Lightning may be the most frequently encountered severe-storm hazard endangering physically active people each year. Millions of lightning flashes strike the

ground annually in the United States, causing nearly 100 deaths and 400 injuries. Three quarters of all lightning casualties occur between May and September, and nearly four fifths occur between 10:00 AM and 7:00 PM, which coincides with the hours for most athletic or recreational activities. Additionally, lightning casualties from sports and recreational activities have risen alarmingly in recent decades.

Recommendations. The National Athletic Trainers' Association recommends a proactive approach to lightning safety, including the implementation of a lightning-safety policy that identifies safe locations for shelter from the lightning hazard. Further components of this policy are monitoring local weather forecasts, designating a weather watcher, and establishing a chain of command. Additionally, a flash-to-bang count of 30 seconds or more should be used as a minimal determinant of when to suspend activities. Waiting 30 minutes or longer after the last flash of lightning or sound of thunder is recommended before athletic or recreational activities are resumed. Lightning safety strategies include avoiding shelter under trees, avoiding open fields and spaces, and suspending the use of land-line telephones during thunderstorms. Also outlined in this document are the prehospital care guidelines for triaging and treating lightning-strike victims. It is important to evaluate victims quickly for apnea, asystole, hypothermia, shock, fractures, and burns. Cardiopulmonary resuscitation is effective in resuscitating pulseless victims of lightning strike. Maintenance of cardiopulmonary resuscitation and first-aid certification should be required of all persons involved in sports and recreational activities. (12/00)

LONG-TERM CARDIOVASCULAR TOXICITY IN CHILDREN, ADOLESCENTS, AND YOUNG ADULTS WHO RECEIVE CANCER THERAPY: PATHOPHYSIOLOGY, COURSE, MONITORING, MANAGEMENT, PREVENTION, AND RESEARCH DIRECTIONS: A SCIENTIFIC STATEMENT FROM THE AMERICAN HEART ASSOCIATION
American Heart Association (5/13)

THE MANAGEMENT OF HYPOTENSION IN THE VERY-LOW-BIRTH-WEIGHT INFANT: GUIDELINE FOR PRACTICE

National Association of Neonatal Nurses

ABSTRACT. This guideline, released in 2011, focuses on the clinical management of systemic hypotension in the very-low-birth-weight (VLBW) infant during the first 3 days of postnatal life. (2011)

MEETING OF THE STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION, APRIL 2012—CONCLUSIONS AND RECOMMENDATIONS

World Health Organization (5/12) (The AAP endorses the recommendation pertaining to the use of thimerosal in vaccines.)

MENTAL HEALTH AND SUBSTANCE USE SCREENING AND ASSESSMENT OF CHILDREN IN FOSTER CARE
American Academy of Child and Adolescent Psychiatry and Child Welfare League of America (2003)

MULTILINGUAL CHILDREN: BEYOND MYTHS AND TOWARD BEST PRACTICES

Society for Research in Child Development

ABSTRACT. Multilingualism is an international fact of life and increasing in the United States. Multilingual families are exceedingly diverse, and policies relevant to them should take this into account. The quantity and quality of a child's exposure to responsive conversation spoken by fluent adults predicts both monolingual and multilingual language and literacy achievement. Contexts supporting optimal multilingualism involve early exposure to high quality conversation in each language, along with continued support for speaking both languages. Parents who are not fluent in English should not be told to speak English instead of their native language to their children; children require fluent input, and fluent input in another language will transfer to learning a second or third language. Messages regarding optimal multilingual practices should be made available to families using any and all available methods for delivering such information, including home visitation programs, healthcare settings, center-based early childhood programs, and mass media. (2013)

NATIONAL ADOPTION CENTER: OPEN RECORDS

National Adoption Center

The National Adoption Center believes that it is an inalienable right of all citizens, including adopted adults, to have unencumbered access to their original birth certificates. In keeping with this position, we believe that copies of both the original and the amended birth certificate should be given to the adoptive family at the time of finalization unless specifically denied by the birthparents. In any case, the National Adoption Center advocates that the adoptee, at age 18, be granted access to his/her original birth certificate. (6/00)

NEONATAL ENCEPHALOPATHY AND NEUROLOGIC OUTCOME, SECOND EDITION

American College of Obstetricians and Gynecologists Task Force on Neonatal Encephalopathy

In the first edition of this report, the Task Force on Neonatal Encephalopathy and Cerebral Palsy outlined criteria deemed essential to establish a causal link between intrapartum hypoxic events and cerebral palsy. It is now known that there are multiple potential causal pathways that lead to cerebral palsy in term infants (see Fig 1), and the signs and symptoms of neonatal encephalopathy may range from mild to severe, depending on the nature and timing of the brain injury. Thus, for the current edition, the Task Force on Neonatal Encephalopathy determined that a broader perspective may be more fruitful. This conclusion reflects the sober recognition that knowledge gaps still preclude a definitive test or set of markers that accurately identifies, with high sensitivity and specificity, an infant in whom neonatal encephalopathy is attributable to an acute intrapartum event. The information necessary for assessment of likelihood can be derived from a comprehensive evaluation of all potential contributing factors in cases of neonatal encephalopathy. This is the broader perspective championed in the current report. If a comprehensive etiologic evaluation is not possible, the term hypoxic-ischemic encephalopathy should best be replaced

by neonatal encephalopathy because neither hypoxia nor ischemia can be assumed to have been the unique initiating causal mechanism. The title of this report has been changed from Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology to Neonatal Encephalopathy and Neurologic Outcome to indicate that an array of developmental outcomes may arise after neonatal encephalopathy in addition to cerebral palsy. (4/14)

NEURODEVELOPMENTAL OUTCOMES IN CHILDREN WITH CONGENITAL HEART DISEASE: EVALUATION AND MANAGEMENT: A SCIENTIFIC STATEMENT FROM THE AMERICAN HEART ASSOCIATION

American Heart Association (7/12)

NONINHERITED RISK FACTORS AND CONGENITAL CARDIOVASCULAR DEFECTS: CURRENT KNOWLEDGE

American Heart Association

ABSTRACT. Prevention of congenital cardiovascular defects has been hampered by a lack of information about modifiable risk factors for abnormalities in cardiac development. Over the past decade, there have been major breakthroughs in the understanding of inherited causes of congenital heart disease, including the identification of specific genetic abnormalities for some types of malformations. Although relatively less information has been available on noninherited modifiable factors that may have an adverse effect on the fetal heart, there is a growing body of epidemiological literature on this topic. This statement summarizes the currently available literature on potential fetal exposures that might alter risk for cardiovascular defects. Information is summarized for periconceptional multivitamin or folic acid intake, which may reduce the risk of cardiac disease in the fetus, and for additional types of potential exposures that may increase the risk, including maternal illnesses, maternal therapeutic and nontherapeutic drug exposures, environmental exposures, and paternal exposures. Information is highlighted regarding definitive risk factors such as maternal rubella; phenylketonuria; pregestational diabetes; exposure to thalidomide, vitamin A congeners, or retinoids; and indomethacin tocolysis. Caveats regarding interpretation of possible exposure-outcome relationships from case-control studies are given because this type of study has provided most of the available information. Guidelines for prospective parents that could reduce the likelihood that their child will have a major cardiac malformation are given. Issues related to pregnancy monitoring are discussed. Knowledge gaps and future sources of new information on risk factors are described. (*Circulation*. 2007;115:2995–3014.) (6/07)

PEDIATRIC CARE IN THE EMERGENCY DEPARTMENT

Society for Academic Emergency Medicine

ABSTRACT. Physicians who have successfully completed an accredited Emergency Medicine residency and are certified in emergency medicine by the American Board of Emergency Medicine (ABEM) or the American Osteopathic Board of Emergency Medicine (AOBEM) ABEM/AOBEM or those who are certified in pediatric emergency medicine by ABEM or the American Board of Pediatrics (ABP) possess the knowledge and skills

required to provide quality emergency medical care to children of all ages for a wide variety of illnesses, injuries or poisonings. To provide quality care, the emergency physician must have all necessary and age-appropriate medical equipment readily available. The emergency physician must also have access via consultation, admission, or transfer, to appropriate specialty and sub-specialty physicians, to who will provide any needed patient care after emergency department treatment. Physically separated care areas for children are not mandatory in order to provide high-quality care to patients of all ages. Although physically separate care areas for children are ideal, they are not mandatory to provide high-quality care. (11/03)

PREVENTION AND CONTROL OF MENINGOCOCCAL DISEASE: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention

SUMMARY. Meningococcal disease describes the spectrum of infections caused by *Neisseria meningitidis*, including meningitis, bacteremia, and bacteremic pneumonia. Two quadrivalent meningococcal polysaccharide-protein conjugate vaccines that provide protection against meningococcal serogroups A, C, W, and Y (MenACWY-D [Menactra, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania] and MenACWY-CRM [Menveo, manufactured by Novartis Vaccines, Cambridge, Massachusetts]) are licensed in the United States for use among persons aged 2 through 55 years. MenACWY-D also is licensed for use among infants and toddlers aged 9 through 23 months. Quadrivalent meningococcal polysaccharide vaccine (MPSV4 [Menomune, manufactured by sanofi pasteur, Inc., Swiftwater, Pennsylvania]) is the only vaccine licensed for use among persons aged ≥56 years. A bivalent meningococcal polysaccharide protein conjugate vaccine that provides protection against meningococcal serogroups C and Y along with *Haemophilus influenzae* type b (Hib) (Hib-MenCY-TT [MenHibrix, manufactured by GlaxoSmithKline Biologicals, Rixensart, Belgium]) is licensed for use in children aged 6 weeks through 18 months.

This report compiles and summarizes all recommendations from CDC's Advisory Committee on Immunization Practices (ACIP) regarding prevention and control of meningococcal disease in the United States, specifically the changes in the recommendations published since 2005 (CDC. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2005;54 Adobe PDF file [No. RR-7]). As a comprehensive summary of previously published recommendations, this report does not contain any new recommendations; it is intended for use by clinicians as a resource. ACIP recommends routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years. ACIP also recommends routine vaccination for persons at increased risk for meningococcal disease (i.e., persons who have persistent complement component deficiencies, persons who have anatomic or functional asplenia, microbiologists who routinely are exposed to isolates of *N. meningitidis*,

military recruits, and persons who travel to or reside in areas in which meningococcal disease is hyperendemic or epidemic). Guidelines for antimicrobial chemoprophylaxis and for evaluation and management of suspected outbreaks of meningococcal disease also are provided. (3/13)

PREVENTION OF RHEUMATIC FEVER AND DIAGNOSIS AND TREATMENT OF ACUTE STREPTOCOCCAL PHARYNGITIS

American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee of the Council on Cardiovascular Disease in the Young; Interdisciplinary Council on Functional Genomics and Translational Biology; and Interdisciplinary Council on Quality of Care and Outcomes Research

ABSTRACT. Primary prevention of acute rheumatic fever is accomplished by proper identification and adequate antibiotic treatment of group A α -hemolytic streptococcal (GAS) tonsillopharyngitis. Diagnosis of GAS pharyngitis is best accomplished by combining clinical judgment with diagnostic test results, the criterion standard of which is the throat culture. Penicillin (either oral penicillin V or injectable benzathine penicillin) is the treatment of choice, because it is cost-effective, has a narrow spectrum of activity, and has long-standing proven efficacy, and GAS resistant to penicillin have not been documented. For penicillin-allergic individuals, acceptable alternatives include a narrow-spectrum oral cephalosporin, oral clindamycin, or various oral macrolides or azalides. The individual who has had an attack of rheumatic fever is at very high risk of developing recurrences after subsequent GAS pharyngitis and needs continuous antimicrobial prophylaxis to prevent such recurrences (secondary prevention). The recommended duration of prophylaxis depends on the number of previous attacks, the time elapsed since the last attack, the risk of exposure to GAS infections, the age of the patient, and the presence or absence of cardiac involvement. Penicillin is again the agent of choice for secondary prophylaxis, but sulfadiazine or a macrolide or azalide are acceptable alternatives in penicillin-allergic individuals. This report updates the 1995 statement by the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee. It includes new recommendations for the diagnosis and treatment of GAS pharyngitis, as well as for the secondary prevention of rheumatic fever, and classifies the strength of the recommendations and level of evidence supporting them. (2/09)

PROTECTING ADOLESCENTS: ENSURING ACCESS TO CARE AND REPORTING SEXUAL ACTIVITY AND ABUSE

Society for Adolescent Medicine (11/04)

REPORT OF THE NATIONAL CONSENSUS CONFERENCE ON FAMILY PRESENCE DURING PEDIATRIC CARDIOPULMONARY RESUSCITATION AND PROCEDURES

Ambulatory Pediatric Association

INTRODUCTION. The National Consensus Conference on Family Presence during Pediatric Cardiopulmonary Resuscitation and Procedures was held in Washington, DC, on September 7–8, 2003. The concept, funding,

planning and organization for the conference were the Ambulatory Pediatric Association (APA) Presidential Project of James Seidel, M.D., Ph.D. Dr. Seidel was in the final stages of preparation for chairing the conference when he died on July 25, 2003. In Dr. Seidel's absence, the conference was chaired by Deborah Parkman Henderson R.N., PhD, his co-investigator, and Jane F. Knapp, M.D, a colleague.

The National Consensus Conference on Family Presence during Pediatric Procedures and Cardiopulmonary Resuscitation was funded by a grant to the APA from the Maternal Child Health Bureau (MCHB) Partnership for Children. This meeting brought together a panel of over 20 appointed representatives from a multidisciplinary, diverse group of national organizations interested in the emergency care of children. The conference was part of a multiphase process designed with the goal of publishing consensus guidelines useful for defining policy regarding family presence (FP) during pediatric procedures and CPR in the Emergency Department (ED). It is also possible that the consensus panel recommendations could be applied to other settings.

Panel members completed a review of the literature prior to attending the conference. This review, along with results of a pre-conference questionnaire, formed the basis of the discussion during the conference. During the two day conference the participants completed the outline of the guidelines presented here. We believe these recommendations are a powerful testimony to Dr. Seidel's vision for promoting FP through multidisciplinary consensus building. Beyond that vision, however, we hope that the guidelines will make a difference in improving the quality of children's health care. (9/03)

RESPONSE TO CARDIAC ARREST AND SELECTED LIFE-THREATENING MEDICAL EMERGENCIES: THE MEDICAL EMERGENCY RESPONSE PLAN FOR SCHOOLS. A STATEMENT FOR HEALTHCARE PROVIDERS, POLICYMAKERS, SCHOOL ADMINISTRATORS, AND COMMUNITY LEADERS

American Heart Association (1/04)

SAFE AT SCHOOL CAMPAIGN STATEMENT OF PRINCIPLES

American Diabetes Association (endorsed 2/06)

SCREENING FOR IDIOPATHIC SCOLIOSIS IN ADOLESCENTS

Pediatric Orthopaedic Society of North America, American Academy of Orthopaedic Surgeons, and Scoliosis Research Society

EXECUTIVE SUMMARY. Many states mandate school screening to identify children at risk for scoliosis, though recent studies have cast some controversy on the effectiveness of routine scoliosis screening. Previous studies have both supported and discouraged routine screening.

Prevention of severe scoliosis is a major commitment of physicians caring for children with spinal deformities. For this reason, the American Academy of Orthopaedic Surgeons (AAOS), the Scoliosis Research Society (SRS), the Pediatric Orthopaedic Society of North America

(POSNA), and the American Academy of Pediatrics (AAP) convened a task force to examine issues related to scoliosis screening and to put forth the present information statement. The societies acknowledge the important role of a systematic review of the literature as well as the role of consensus expert opinion in the common situation where the available evidence does not yet exist to speak definitely for, or against, an evaluation or intervention.

Costs involved with scoliosis screening are relatively low on a societal level and may justify the possibility of preventing surgery in adolescents with scoliosis. Adolescents without significant spinal deformity who are referred to a specialist for evaluation often do not require radiographs. For those who do need radiographic evaluation, it is important to know that the radiation exposure using current-day radiographic techniques, including digital radiography, is significantly smaller than in the past.

Opponents to scoliosis screening have focused on concerns about a low predictive value of screening and the cost-effectiveness of referral. There have also been concerns about the possibility of unnecessary treatment, including brace use, and the effect of exposure to radiation when radiographs are obtained.

With regard to early treatment in those adolescents detected with moderate scoliosis, the available data neither definitively support nor refute the efficacy of bracing. To most effectively answer this, a well-organized level I study is needed. Such a study, a five-year multicenter randomized controlled trial of bracing sponsored by the National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH/NIAMS), is currently under way.

In 1996, the United States Preventive Services Task Force (USPSTF) concluded that there was insufficient evidence to make a recommendation for, or against, screening. However, in 2004, the USPSTF changed their position and recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis. The AAOS, SRS, POSNA, and AAP have concerns that this change in position by the USPSTF came in the absence of any significant change in the available literature, in the absence of any change in position statements by the AAOS, SRS, POSNA, and AAP, and in the absence of any significant input from specialists who commonly care for children with scoliosis.

As the primary care providers for adolescents with idiopathic scoliosis, the AAOS, SRS, POSNA, and AAP do not support any recommendation against scoliosis screening, given the available literature. (1/08)

SELECTED ISSUES FOR THE ADOLESCENT ATHLETE AND THE TEAM PHYSICIAN: A CONSENSUS STATEMENT

American Academy of Family Physicians, American Academy of Orthopaedic Surgeons, American College of Sports Medicine, American Medical Society for Sports Medicine, American Orthopaedic Society for Sports Medicine, and American Osteopathic Academy of Sports Medicine

GOAL. The goal of this document is to help the team physician improve the care of the adolescent athlete by understanding the medical, musculoskeletal and psycho-

logical factors common in this age group. To accomplish this goal, the team physician should have knowledge of and be involved with:

Musculoskeletal injuries of the adolescent athlete, specifically those to the shoulder, knee, elbow and spine

Medical conditions of the adolescent athlete, especially those pertaining to infectious diseases, concussion, and nutrition and supplementation

Psychological issues related to sports specialization and overtraining. (11/08)

SKIING AND SNOWBOARDING INJURY PREVENTION

Canadian Paediatric Society

ABSTRACT. Skiing and snowboarding are popular recreational and competitive sport activities for children and youth. Injuries associated with both activities are frequent and can be serious. There is new evidence documenting the benefit of wearing helmets while skiing and snowboarding, as well as data refuting suggestions that helmet use may increase the risk of neck injury. There is also evidence to support using wrist guards while snowboarding. There is poor uptake of effective preventive measures such as protective equipment use and related policy. Physicians should have the information required to counsel children, youth and families regarding safer snow sport participation, including helmet use, wearing wrist guards for snowboarding, training and supervision, the importance of proper equipment fitting and binding adjustment, sun safety and avoiding substance use while on the slopes. (1/12)

SUPPLEMENT TO THE JCIH 2007 POSITION STATEMENT: PRINCIPLES AND GUIDELINES FOR EARLY INTERVENTION AFTER CONFIRMATION THAT A CHILD IS DEAF OR HARD OF HEARING

Joint Committee on Infant Hearing

PREFACE. This document is a supplement to the recommendations in the year 2007 position statement of the Joint Committee on Infant Hearing (JCIH) and provides comprehensive guidelines for early hearing detection and intervention (EHDI) programs on establishing strong early intervention (EI) systems with appropriate expertise to meet the needs of children who are deaf or hard of hearing (D/HH).

EI services represent the purpose and goal of the entire EHDI process. Screening and confirmation that a child is D/HH are largely meaningless without appropriate, individualized, targeted and high-quality intervention. For the infant or young child who is D/HH to reach his or her full potential, carefully designed individualized intervention must be implemented promptly, utilizing service providers with optimal knowledge and skill levels and providing services on the basis of research, best practices, and proven models.

The delivery of EI services is complex and requires individualization to meet the identified needs of the child and family. Because of the diverse needs of the population of children who are D/HH and their families, well-controlled intervention studies are challenging. At this time, few comparative effectiveness studies have been conducted. Randomized controlled trials are particularly difficult for ethical reasons, making it challenging to estab-

lish causal links between interventions and outcomes. EI systems must partner with colleagues in research to document what works for children and families and to strengthen the evidence base supporting practices.

Despite limitations and gaps in the evidence, the literature does contain research studies in which all children who were D/HH had access to the same well-defined EI service. These studies indicate that positive outcomes are possible, and they provide guidance about key program components that appear to promote these outcomes. This EI services document, drafted by teams of professionals with extensive expertise in EI programs for children who are D/HH and their families, relied on literature searches, existing systematic reviews, and recent professional consensus statements in developing this set of guidelines.

Terminology presented a challenge throughout document development. The committee noted that many of the frequently occurring terms necessary within the supplement may not reflect the most contemporary understanding and/or could convey inaccurate meaning. Rather than add to the lack of clarity or consensus and to avoid introducing new terminology to stakeholders, the committee opted to use currently recognized terms consistently herein and will monitor the emergence and/or development of new descriptors before the next JCIH consensus statement.

For purposes of this supplement:

- Language refers to all spoken and signed languages.
- Early intervention (EI), according to part C of the Individuals with Disabilities Education Improvement Act (IDEA) of 2004, is the process of providing services, education, and support to young children who are deemed to have an established condition, those who are evaluated and deemed to have a diagnosed physical or mental condition (with a high probability of resulting in a developmental delay), those who have an existing delay, or those who are at risk of developing a delay or special need that may affect their development or impede their education.
- Communication is used in lieu of terms such as communication options, methods, opportunities, approaches, etc.
- Deaf or hard of hearing (D/HH) is intended to be inclusive of all children with congenital and acquired hearing loss, unilateral and bilateral hearing loss, all degrees of hearing loss from minimal to profound, and all types of hearing loss (sensorineural, auditory neuropathy spectrum disorder, permanent conductive, and mixed).
- Core knowledge and skills is used to describe the expertise needed to provide appropriate EI that will optimize the development and well-being of infants/children and their families. Core knowledge and skills will differ according to the roles of individuals within the EI system (eg, service coordinator or EI provider).

This supplement to JCIH 2007 focuses on the practices of EI providers outside of the primary medical care and specialty medical care realms, rather than including the full spectrum of necessary medical, audiologic, and educational interventions. For more information about the recommendations for medical follow-up, primary care surveillance for related medical conditions, and specialty medical care and monitoring, the reader is encouraged to reference the year 2007 position statement of the JCIH as well as any subsequent revision. When an infant is confirmed to be D/HH, the importance of ongoing medical and audiologic management and surveillance both in the medical home and with the hearing health professionals, the otolaryngologist and the audiologist, cannot be overstated. A comprehensive discussion of those services is beyond the scope of this document. (3/13)

TARGETED TUBERCULIN TESTING AND TREATMENT OF LATENT TUBERCULOSIS INFECTION

American Thoracic Society and Centers for Disease Control and Prevention (4/00) (The AAP endorses and accepts as its policy the sections of this statement as they relate to infants and children.)

TIMING OF UMBILICAL CORD CLAMPING AFTER BIRTH

American College of Obstetricians and Gynecologists Committee on Obstetric Practice (12/12)

UPDATE ON JAPANESE ENCEPHALITIS VACCINE FOR CHILDREN—UNITED STATES, MAY 2011

Centers for Disease Control and Prevention

Inactivated mouse brain-derived Japanese encephalitis (JE) vaccine (JE-MB [manufactured as JE-Vax]), the only JE vaccine that is licensed for use in children in the United States, is no longer available. This notice provides updated information regarding options for obtaining JE vaccine for U.S. children. (8/11)

WEIGHING PEDIATRIC PATIENTS IN KILOGRAMS

Emergency Nurses Association (3/12)

APPENDIX 1

Policies by Committee
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AMERICAN ACADEMY OF PEDIATRICS

Policies by Committee

ADOLESCENT SLEEP WORKING GROUP

Insufficient Sleep in Adolescents and Young Adults:
An Update on Causes and Consequences (Technical Report) (joint with Committee on Adolescence), 8/14
School Start Times for Adolescents (joint with Committee on Adolescence and Council on School Health), 8/14

BLACK BOX WORKING GROUP

Cardiovascular Monitoring and Stimulant Drugs for Attention-Deficit/Hyperactivity Disorder (joint with Section on Cardiology and Cardiac Surgery), 8/08

BOARD OF DIRECTORS

Ritual Genital Cutting of Female Minors, 6/10

BRIGHT FUTURES PERIODICITY SCHEDULE WORK-GROUP

2014 Recommendations for Pediatric Preventive Health Care (joint with Committee on Practice and Ambulatory Medicine), 2/14

BRIGHT FUTURES STEERING COMMITTEE

Identifying Infants and Young Children With Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening (joint with Council on Children With Disabilities, Section on Developmental and Behavioral Pediatrics, and Medical Home Initiatives for Children With Special Needs Project Advisory Committee), 7/06, reaffirmed 12/09, 8/14

Recommendations for Preventive Pediatric Health Care (joint with Committee on Practice and Ambulatory Medicine), 12/07, reaffirmed 1/11

BRONCHIOLITIS GUIDELINES COMMITTEE

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (joint with Committee on Infectious Diseases), 7/14

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (Technical Report) (joint with Committee on Infectious Diseases), 7/14

CARDIAC SURGERY EXECUTIVE COMMITTEE

Endorsement of Health and Human Services Recommendation for Pulse Oximetry Screening for Critical Congenital Heart Disease (joint with Section on Cardiology), 12/11

CHILD AND ADOLESCENT HEALTH ACTION GROUP (FORMERLY COUNCIL ON CHILD AND ADOLESCENT HEALTH)

Age Limits of Pediatrics, 5/88, reaffirmed 9/92, 1/97, 3/02, 1/06, 10/11

COMMITTEE ON ADOLESCENCE

Achieving Quality Health Services for Adolescents, 6/08, reaffirmed 3/13

Adolescent Pregnancy: Current Trends and Issues (Clinical Report), 7/05

Adolescent Pregnancy: Current Trends and Issues—Addendum, 4/14

Adolescents and Human Immunodeficiency Virus Infection: The Role of the Pediatrician in Prevention and Intervention (joint with Committee on Pediatric AIDS), 1/01, reaffirmed 10/03, 1/05

The Adolescent's Right to Confidential Care When Considering Abortion, 5/96, reaffirmed 5/99, 11/02

Care of Adolescent Parents and Their Children (Clinical Report) (joint with Committee on Early Childhood), 11/12

Care of the Adolescent Sexual Assault Victim (Clinical Report), 8/08

Collaborative Role of the Pediatrician in the Diagnosis and Management of Bipolar Disorder in Adolescents (Clinical Report), 11/12

Condom Use by Adolescents, 10/13

Contraception for Adolescents, 9/14

Contraception for Adolescents (Technical Report), 9/14

Counseling the Adolescent About Pregnancy Options, 5/98, reaffirmed 1/01, 1/06

Emergency Contraception, 11/12

Emergency Contraception: Addendum, 2/14

Excessive Sleepiness in Adolescents and Young Adults: Causes, Consequences, and Treatment Strategies (Technical Report) (joint with Working Group on Sleepiness in Adolescents/Young Adults), 6/05

Gynecologic Examination for Adolescents in the Pediatric Office Setting (Clinical Report), 8/10, reaffirmed 5/13

Health Care for Youth in the Juvenile Justice System, 11/11

Identification and Management of Eating Disorders in Children and Adolescents (Clinical Report), 11/10

Insufficient Sleep in Adolescents and Young Adults: An Update on Causes and Consequences (Technical Report) (joint with Adolescent Sleep Working Group), 8/14

Legalization of Marijuana: Potential Impact on Youth (joint with Committee on Substance Abuse), 6/04

Legalization of Marijuana: Potential Impact on Youth (Technical Report) (joint with Committee on Substance Abuse), 6/04

Male Adolescent Sexual and Reproductive Health Care (Clinical Report), 11/11

Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign (Clinical Report) (joint with American College of Obstetricians and Gynecologists), 11/06

Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth, 6/13

Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth (Technical Report), 6/13

School Start Times for Adolescents (joint with Adolescence Sleep Working Group and Council on School Health), 8/14

Screening for Nonviral Sexually Transmitted Infections in Adolescents and Young Adults (joint with Society for Adolescent Health and Medicine) 6/14

Secondhand and Prenatal Tobacco Smoke Exposure (Technical Report) (joint with Committee on Environmental Health and Committee on Native American Child Health), 10/09, reaffirmed 5/14

Sexual Orientation and Adolescents (Clinical Report), 6/04

Sexuality Education for Children and Adolescents (joint with Committee on Psychosocial Aspects of Child and Family Health), 8/01, reaffirmed 10/04

Standards for Health Information Technology to Ensure Adolescent Privacy (joint with Council on Clinical Information Technology), 10/12

Suicide and Suicide Attempts in Adolescents (Clinical Report), 9/07

The Teen Driver (joint with Committee on Injury, Violence, and Poison Prevention), 12/06, reaffirmed 6/10

Tobacco Use: A Pediatric Disease (joint with Committee on Environmental Health, Committee on Substance Abuse, and Committee on Native American Child Health), 10/09, reaffirmed 5/13

Underinsurance of Adolescents: Recommendations for Improved Coverage of Preventive, Reproductive, and Behavioral Health Care Services (joint with Committee on Child Health Financing), 12/08

COMMITTEE ON BIOETHICS

Children as Hematopoietic Stem Cell Donors, 1/10

Communicating With Children and Families: From Everyday Interactions to Skill in Conveying Distressing Information (Technical Report), 5/08, reaffirmed 5/11

Conflicts Between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding, 10/13

Consent for Emergency Medical Services for Children and Adolescents (joint with Committee on Pediatric Emergency Medicine), 7/11

Do-Not-Resuscitate Orders for Pediatric Patients Who Require Anesthesia and Surgery (Clinical Report) (joint with Section on Surgery and Section on Anesthesia and Pain Medicine), 12/04, reaffirmed 1/09, 10/12

Ethical and Policy Issues in Genetic Testing and Screening of Children (joint with Committee on Genetics and American College of Medical Genetics and Genomics), 2/13

Ethical Controversies in Organ Donation After Circulatory Death, 4/13

Ethical Issues With Genetic Testing in Pediatrics, 6/01, reaffirmed 1/05, 1/09

Ethics and the Care of Critically Ill Infants and Children, 7/96, reaffirmed 10/99, 6/03

Forgoing Life-Sustaining Medical Treatment in Abused Children (joint with Committee on Child Abuse and Neglect), 11/00, reaffirmed 6/03, 10/06, 4/09

Forgoing Medically Provided Nutrition and Hydration in Children (Clinical Report), 7/09, reaffirmed 1/14

Guidelines on Forgoing Life-Sustaining Medical Treatment, 3/94, reaffirmed 11/97, 10/00, 1/04, 1/09, 10/12

Honoring Do-Not-Attempt-Resuscitation Requests in Schools (joint with Council on School Health), 4/10, reaffirmed 7/13

Human Embryonic Stem Cell (hESC) and Human Embryo Research (joint with Committee on Pediatric Research), 10/12

Informed Consent, Parental Permission, and Assent in Pediatric Practice, 2/95, reaffirmed 11/98, 11/02, 10/06, 5/11

Institutional Ethics Committees, 1/01, reaffirmed 1/04, 1/09, 10/12, 7/14

Maternal-Fetal Intervention and Fetal Care Centers (Clinical Report) (joint with American College of Obstetricians and Gynecologists), 7/11

Minors as Living Solid-Organ Donors (Clinical Report), 8/08, reaffirmed 5/11

Palliative Care for Children (joint with Committee on Hospital Care), 8/00, reaffirmed 6/03, 10/06, 2/12

Pediatrician-Family-Patient Relationships: Managing the Boundaries, 11/09, reaffirmed 1/14

Physician Refusal to Provide Information or Treatment on the Basis of Claims of Conscience, 11/09, reaffirmed 1/14

Preservation of Fertility in Pediatric and Adolescent Patients With Cancer (Technical Report) (joint with Section on Hematology/Oncology and Section on Surgery), 5/08, reaffirmed 2/12

Professionalism in Pediatrics: Statement of Principles, 10/07, reaffirmed 5/11

Professionalism in Pediatrics (Technical Report), 10/07, reaffirmed 5/11

Religious Objections to Medical Care, 2/97, reaffirmed 10/00, 6/03, 10/06, 5/09

Responding to Parental Refusals of Immunization of Children (Clinical Report), 5/05, reaffirmed 1/09

COMMITTEE ON CHILD ABUSE AND NEGLECT

Abusive Head Trauma in Infants and Children, 4/09, reaffirmed 3/13

Caregiver-Fabricated Illness in a Child: A Manifestation of Child Maltreatment (Clinical Report), 8/13

Child Abuse, Confidentiality, and the Health Insurance Portability and Accountability Act, 12/09, reaffirmed 1/14

Child Fatality Review (joint with Committee on Injury, Violence, and Poison Prevention and Council on Community Pediatrics), 8/10, reaffirmed 5/14

Distinguishing Sudden Infant Death Syndrome From Child Abuse Fatalities (Clinical Report) (joint with National Association of Medical Examiners), 7/06, reaffirmed 4/09, 3/13

Evaluating Children With Fractures for Child Physical Abuse (Clinical Report), (joint with Section on Radiology; Section on Endocrinology; Section on Orthopaedics; and Society for Pediatric Radiology), 1/14

Evaluating for Suspected Child Abuse: Conditions That Predispose to Bleeding (Technical Report) (joint with Section on Hematology/Oncology), 3/13

Evaluating Infants and Young Children With Multiple Fractures (Clinical Report), 9/06

Evaluation for Bleeding Disorders in Suspected Child Abuse (Clinical Report) (joint with Section on Hematology/Oncology), 3/13

The Evaluation of Children in the Primary Care Setting When Sexual Abuse Is Suspected (Clinical Report), 7/13

The Evaluation of Sexual Behaviors in Children (Clinical Report), 8/09, reaffirmed 3/13

Evaluation of Suspected Child Physical Abuse (Clinical Report), 6/07, reaffirmed 5/12

The Eye Examination in the Evaluation of Child Abuse (Clinical Report) (joint with Section on Ophthalmology), 7/10

Failure to Thrive as a Manifestation of Child Neglect (Clinical Report) (joint with Committee on Nutrition), 11/05, reaffirmed 1/09

Forgoing Life-Sustaining Medical Treatment in Abused Children (joint with Committee on Bioethics), 11/00, reaffirmed 6/03, 10/06, 4/09

Intimate Partner Violence: The Role of the Pediatrician (Clinical Report) (joint with Committee on Injury, Violence, and Poison Prevention), 4/10, reaffirmed 1/14

Maltreatment of Children With Disabilities (Clinical Report) (joint with Council on Children With Disabilities), 5/07, reaffirmed 1/11

Oral and Dental Aspects of Child Abuse and Neglect (Clinical Report) (joint with American Academy of Pediatric Dentistry), 12/05, reaffirmed 1/09, 1/14

The Pediatrician's Role in Child Maltreatment Prevention (Clinical Report), 9/10, 1/14

Protecting Children From Sexual Abuse by Health Care Providers, 6/11

Psychological Maltreatment (Clinical Report) (joint with American Academy of Child and Adolescent Psychiatry), 7/12

Recognizing and Responding to Medical Neglect (Clinical Report), 12/07, reaffirmed 1/11

Understanding the Behavioral and Emotional Consequences of Child Abuse (Clinical Report) (joint with Section on Adoption and Foster Care, American Academy of Child and Adolescent Psychiatry, and National Center for Child Traumatic Stress), 9/08, reaffirmed 8/12

When Is Lack of Supervision Neglect? (Clinical Report), 9/06

COMMITTEE ON CHILD HEALTH FINANCING

Children's Health Insurance Program (CHIP): Accomplishments, Challenges, and Policy Recommendations, 2/14

Essential Contractual Language for Medical Necessity in Children, 7/13

Financing of Pediatric Home Health Care (joint with Section on Home Care), 8/06

Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults, 10/13

High-Deductible Health Plans, 4/14

High-Deductible Health Plans and the New Risks of Consumer-Driven Health Insurance Products, 3/07

Improving Substance Abuse Prevention, Assessment, and Treatment Financing for Children and Adolescents (joint with Committee on Substance Abuse), 10/01

Medicaid Policy Statement, 4/13

Model Contractual Language for Medical Necessity for Children, 7/05, reaffirmed 10/11

Payment for Telephone Care (joint with Section on Telephone Care), 10/06

Principles of Health Care Financing, 10/10, reaffirmed 4/13

Scope of Health Care Benefits for Children From Birth Through Age 26, 11/11

State Children's Health Insurance Program Achievements, Challenges, and Policy Recommendations, 6/07

Underinsurance of Adolescents: Recommendations for Improved Coverage of Preventive, Reproductive, and Behavioral Health Care Services (joint with Committee on Adolescence), 12/08

COMMITTEE ON CODING AND NOMENCLATURE

Application of the Resource-Based Relative Value Scale System to Pediatrics, 5/14

COMMITTEE ON DRUGS

Fever and Antipyretic Use in Children (Clinical Report) (joint with Section on Clinical Pharmacology and Therapeutics), 2/11

Generic Prescribing, Generic Substitution, and Therapeutic Substitution, 5/87, reaffirmed 6/93, 5/96, 6/99, 5/01, 5/05, 10/08, 10/12

Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations (Clinical Report) (joint with Committee on Pediatric Research), 3/10, reaffirmed 1/14

Neonatal Drug Withdrawal (Clinical Report) (joint with Committee on Fetus and Newborn), 1/12

Off-Label Use of Drugs in Children, 2/14

Preparing for Pediatric Emergencies: Drugs to Consider (Clinical Report), 2/08, reaffirmed 10/11

Recognition and Management of Iatrogenically Induced Opioid Dependence and Withdrawal in Children (Clinical Report) (joint with Section on Anesthesiology and Pain Medicine), 12/13

The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics (Clinical Report), 8/13

Use of Codeine- and Dextromethorphan-Containing Cough Remedies in Children, 6/97, reaffirmed 5/00, 6/03, 10/06

Uses of Drugs Not Described in the Package Insert (Off-Label Uses), 7/02, reaffirmed 10/05

COMMITTEE ON FETUS AND NEWBORN

Advanced Practice in Neonatal Nursing, 5/09, reaffirmed 1/14

Age Terminology During the Perinatal Period, 11/04, reaffirmed 10/07, 11/08, 1/09, 7/14

Antenatal Counseling Regarding Resuscitation at an Extremely Low Gestational Age (Clinical Report), 6/09

The Apgar Score (joint with American College of Obstetricians and Gynecologists), 4/06, reaffirmed 1/09

Assessment and Management of Inguinal Hernia in Infants (Clinical Report) (joint with Section on Surgery), 9/12

Controversies Concerning Vitamin K and the Newborn, 7/03, reaffirmed 5/06, 5/09

Epidemiology and Diagnosis of Health Care–Associated Infections in the NICU (Technical Report) (joint with Committee on Infectious Diseases), 3/12

Guidance on Management of Asymptomatic Neonates Born to Women With Active Genital Herpes Lesions (Clinical Report) (joint with Committee on Infectious Diseases), 1/13

Hospital Discharge of the High-Risk Neonate, 11/08, reaffirmed 5/11

Hospital Stay for Healthy Term Newborns, 1/10

Human Immunodeficiency Virus Screening (joint with Committee on Pediatric AIDS and American College of Obstetricians and Gynecologists), 7/99, reaffirmed 6/02, 5/05, 10/08, 5/12

Hypothermia and Neonatal Encephalopathy (Clinical Report), 5/14

Immersion in Water During Labor and Delivery (Clinical Report), (joint with American College of Obstetricians and Gynecologists), 3/14

“Late-Preterm” Infants: A Population at Risk (Clinical Report), 12/07, reaffirmed 5/10

Levels of Neonatal Care, 8/12

Management of Neonates With Suspected or Proven Early-Onset Bacterial Sepsis (Clinical Report), 4/12

Neonatal Drug Withdrawal (Clinical Report) (joint with Committee on Drugs), 1/12

Noninitiation or Withdrawal of Intensive Care for High-Risk Newborns, 2/07, reaffirmed 5/10

Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation (Technical Report), 9/11, reaffirmed 7/14

Planned Home Birth, 4/13

Postdischarge Follow-up of Infants With Congenital Diaphragmatic Hernia (Clinical Report) (joint with Section on Surgery), 3/08, reaffirmed 5/11

Postnatal Corticosteroids to Prevent or Treat Bronchopulmonary Dysplasia, 9/10, reaffirmed 1/14

Postnatal Glucose Homeostasis in Late-Preterm and Term Infants (Clinical Report), 3/11

Premedication for Nonemergency Endotracheal Intubation in the Neonate (Clinical Report) (joint with Section on Anesthesiology and Pain Medicine), 2/10, reaffirmed 8/13

Prenatal Substance Abuse: Short- and Long-term Effects on the Exposed Fetus (Technical Report) (joint with Committee on Substance Abuse), 2/13

Prevention and Management of Pain in the Neonate: An Update (joint with Section on Surgery and Canadian Paediatric Society), 11/06, reaffirmed 5/10

Recommendations for the Prevention of Perinatal Group B Streptococcal (GBS) Disease (joint with Committee on Infectious Diseases), 8/11

Respiratory Support in Preterm Infants at Birth, 12/13

Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP (joint with Section on Cardiology and Cardiac Surgery and American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research), 8/09

Safe Transportation of Preterm and Low Birth Weight Infants at Hospital Discharge (Clinical Report) (joint with Committee on Injury, Violence, and Poison Prevention), 4/09, reaffirmed 8/13

Standard Terminology for Fetal, Infant, and Perinatal Deaths (Clinical Report), 6/11

Strategies for Prevention of Health Care–Associated Infections in the NICU (Clinical Report) (joint with Committee on Infectious Diseases), 3/12

Surfactant Replacement Therapy for Preterm and Term Neonates With Respiratory Distress (Clinical Report), 12/13

Use of Inhaled Nitric Oxide, 8/00, reaffirmed 4/03, 12/09

Use of Inhaled Nitric Oxide in Preterm Infants (Clinical Report), 12/13

COMMITTEE ON GENETICS

Clinical Genetic Evaluation of the Child With Mental Retardation or Developmental Delays (Clinical Report), 6/06, reaffirmed 5/12

Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays (Clinical Report), 8/14

Congenital Adrenal Hyperplasia (Technical Report) (joint with Section on Endocrinology), 12/00, reaffirmed 10/04

Ethical and Policy Issues in Genetic Testing and Screening of Children (joint with Committee on Bioethics and American College of Medical Genetics and Genomics), 2/13

Folic Acid for the Prevention of Neural Tube Defects, 8/99, reaffirmed 11/02, 1/07, 5/12

Health Care Supervision for Children With Williams Syndrome, 5/01, reaffirmed 5/05, 1/09

Health Supervision for Children With Achondroplasia (Clinical Report), 9/05, reaffirmed 5/12

Health Supervision for Children With Down Syndrome (Clinical Report), 7/11

Health Supervision for Children With Fragile X Syndrome (Clinical Report), 4/11

Health Supervision for Children With Marfan Syndrome (Clinical Report), 9/13

Health Supervision for Children With Neurofibromatosis (Clinical Report), 3/08

Health Supervision for Children With Prader-Willi Syndrome (Clinical Report), 12/10

Health Supervision for Children With Sickle Cell Disease (joint with Section on Hematology/Oncology), 3/02, reaffirmed 1/06, 1/11

Maternal Phenylketonuria, 8/08, reaffirmed 1/13

Molecular Genetic Testing in Pediatric Practice: A Subject Review (Clinical Report), 12/00, reaffirmed 5/07

Newborn Screening Fact Sheets, Introduction to the (Technical Report), 9/06, reaffirmed 1/11

Newborn Screening Fact Sheets (Technical Report), 9/06, reaffirmed 1/11

Update of Newborn Screening and Therapy for Congenital Hypothyroidism (Clinical Report) (joint with Section on Endocrinology, American Thyroid Association, and Lawson Wilkins Pediatric Endocrine Society), 6/06, reaffirmed 12/11

COMMITTEE ON HOSPITAL CARE

Admission and Discharge Guidelines for the Pediatric Patient Requiring Intermediate Care (Clinical Report) (joint with Section on Critical Care and Society of Critical Care Medicine), 5/04, reaffirmed 2/08, 1/13

Child Life Services (joint with Child Life Council), 4/14

Facilities and Equipment for the Care of Pediatric Patients in a Community Hospital (Clinical Report), 5/03, reaffirmed 5/07, 8/13

Guidelines for Developing Admission and Discharge Policies for the Pediatric Intensive Care Unit (Clinical Report) (joint with Section on Critical Care and Society of Critical Care Medicine), 4/99, reaffirmed 5/05, 2/08, 1/13

Medical Staff Appointment and Delineation of Pediatric Privileges in Hospitals (Clinical Report) (joint with Section on Hospital Medicine), 3/12

Palliative Care for Children (joint with Committee on Bioethics), 8/00, reaffirmed 6/03, 10/06, 2/12

Patient- and Family-Centered Care and the Pediatrician's Role (joint with Institute for Patient- and Family-Centered Care), 1/12

Pediatric Observation Units (Clinical Report) (joint with Committee on Pediatric Emergency Medicine), 6/12

Pediatric Organ Donation and Transplantation (joint with Section on Surgery and Section on Critical Care), 3/10, reaffirmed 3/14

Pediatric Palliative Care and Hospice Care Commitments, Guidelines, and Recommendations (joint with Section on Hospice and Palliative Medicine), 10/13

Physicians' Roles in Coordinating Care of Hospitalized Children (Clinical Report) (joint with Section on Hospital Medicine), 9/10

Precertification Process, 8/00, reaffirmed 5/05, 11/08

Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care (joint with Steering Committee on Quality Improvement and Management), 5/11

COMMITTEE ON INFECTIOUS DISEASES

Additional Recommendations for Use of Tetanus Toxoid, Reduced-Content Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap), 9/11

Chemical-Biological Terrorism and Its Impact on Children (joint with Committee on Environmental Health), 9/06, reaffirmed 1/11

Clostridium difficile Infection in Infants and Children, 12/12

Cochlear Implants in Children: Surgical Site Infections and Prevention and Treatment of Acute Otitis Media and Meningitis (joint with Section on Otolaryngology–Head and Neck Surgery), 7/10

Consumption of Raw or Unpasteurized Milk and Milk Products by Pregnant Women and Children (joint with Committee on Nutrition), 12/13

Drinking Water From Private Wells and Risks to Children (joint with Committee on Environmental Health), 5/09, reaffirmed 1/13

Drinking Water From Private Wells and Risks to Children (Technical Report) (joint with Committee on Environmental Health), 5/09, reaffirmed 1/13

Epidemiology and Diagnosis of Health Care–Associated Infections in the NICU (Technical Report) (joint with Committee on Fetus and Newborn), 3/12

Exposure to Nontraditional Pets at Home and to Animals in Public Settings: Risks to Children (Clinical Report), 10/08, reaffirmed 12/11

Guidance on Management of Asymptomatic Neonates Born to Women With Active Genital Herpes Lesions (Clinical Report) (joint with Committee on Fetus and Newborn), 1/13

Head Lice (Clinical Report) (joint with Council on School Health), 7/10

HPV Vaccine Recommendations, 2/12

Immunization for *Streptococcus pneumoniae* Infections in High-Risk Children, 11/14

Immunizing Parents and Other Close Family Contacts in the Pediatric Office Setting (Technical Report) (joint with Committee on Practice and Ambulatory Medicine), 12/11

Infection Prevention and Control in Pediatric Ambulatory Settings, 9/07, reaffirmed 8/10

Interferon- γ Release Assays for Diagnosis of Tuberculosis Infection and Disease in Children (Technical Report), 11/14

Meningococcal Conjugate Vaccines Policy Update: Booster Dose Recommendations, 11/11

Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics (Technical Report) (joint with Committee on Environmental Health), 9/04, reaffirmed 10/08, 4/13

Pediatric Anthrax Clinical Management (Clinical Report) (joint with Disaster Preparedness Advisory Council), 4/14

Pediatric Anthrax Clinical Management: Executive Summary (Clinical Report) (joint with Disaster Preparedness Advisory Council), 4/14

Poliovirus, 9/11

Prevention of Rotavirus Disease: Updated Guidelines for Use of Rotavirus Vaccine, 3/09

Prevention of Varicella: Update of Recommendations for Use of Quadrivalent and Monovalent Varicella Vaccines in Children, 8/11

Principles of Judicious Antibiotic Prescribing for Upper Respiratory Tract Infections in Pediatrics (Clinical Report), 11/13

Rabies-Prevention Policy Update: New Reduced-Dose Schedule, 3/11

Recommendation for Mandatory Influenza Immunization of All Health Care Personnel, 9/10

Recommendations for Administering Hepatitis A Vaccine to Contacts of International Adoptees, 9/11

Recommendations for Prevention and Control of Influenza in Children, 2014–2015, 10/14

Recommendations for the Prevention of Perinatal Group B Streptococcal (GBS) Disease (joint with Committee on Fetus and Newborn), 8/11

Recommendations for the Prevention of *Streptococcus pneumoniae* Infections in Infants and Children: Use of 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Pneumococcal Polysaccharide Vaccine (PPSV23), 5/10

Recommended Childhood and Adolescent Immunization Schedule—United States, 2015, 1/15

Strategies for Prevention of Health Care–Associated Infections in the NICU (Clinical Report) (joint with Committee on Fetus and Newborn), 3/12

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (joint with Bronchiolitis Guidelines Committee), 7/14

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (Technical Report) (joint with Bronchiolitis Guidelines Committee), 7/14

Updated Recommendations on the Use of Meningococcal Vaccines, 7/14

The Use of Systemic and Topical Fluoroquinolones (Clinical Report), 9/11

COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT

Consent by Proxy for Nonurgent Pediatric Care (Clinical Report), 10/10

Dealing With the Parent Whose Judgment Is Impaired by Alcohol or Drugs: Legal and Ethical Considerations (Clinical Report), 9/04, reaffirmed 9/10

Expert Witness Participation in Civil and Criminal Proceedings, 6/09

The Pediatrician and Disaster Preparedness (joint with Committee on Pediatric Emergency Medicine and Task Force on Terrorism), 2/06, reaffirmed 6/09, 9/13

Professional Liability Insurance and Medicolegal Education for Pediatric Residents and Fellows, 8/11

COMMITTEE ON NATIVE AMERICAN CHILD HEALTH

Early Childhood Caries in Indigenous Communities (joint with Canadian Paediatric Society), 5/11

Ethical Considerations in Research With Socially Identifiable Populations (joint with Committee on Community Health Services), 1/04, reaffirmed 10/07, 1/13

Health Equity and Children's Rights (joint with Council on Community Pediatrics), 3/10, reaffirmed 10/13

Inhalant Abuse (Clinical Report) (joint with Committee on Substance Abuse), 5/07

Prevention and Treatment of Type 2 Diabetes Mellitus in Children, With Special Emphasis on American Indian and Alaska Native Children (Clinical Report) (joint with Section on Endocrinology), 10/03, reaffirmed 10/08

The Prevention of Unintentional Injury Among American Indian and Alaska Native Children: A Subject Review (Clinical Report) (joint with Committee on Injury and Poison Prevention), 12/99, reaffirmed 5/03, 1/06, 1/09

Secondhand and Prenatal Tobacco Smoke Exposure (Technical Report) (joint with Committee on Environmental Health and Committee on Adolescence), 10/09, reaffirmed 5/14

Tobacco Use: A Pediatric Disease (joint with Committee on Environmental Health, Committee on Substance Abuse, and Committee on Adolescence), 10/09, reaffirmed 5/13

COMMITTEE ON NUTRITION

Calcium and Vitamin D Requirements of Enterally Fed Preterm Infants (Clinical Report), 4/13

Consumption of Raw or Unpasteurized Milk and Milk Products by Pregnant Women and Children (joint with Committee on Infectious Diseases), 12/13

Diagnosis and Prevention of Iron Deficiency and Iron-Deficiency Anemia in Infants and Young Children (0–3 Years of Age) (Clinical Report), 10/10

Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The Role of Maternal Dietary Restriction, Breastfeeding, Timing of Introduction of Complementary Foods, and Hydrolyzed Formulas (Clinical Report) (joint with Section on Allergy and Immunology), 1/08

Failure to Thrive as a Manifestation of Child Neglect (Clinical Report) (joint with Committee on Child Abuse and Neglect), 11/05, reaffirmed 1/09

Infant Methemoglobinemia: The Role of Dietary Nitrate in Food and Water (Clinical Report) (joint with Committee on Environmental Health), 9/05, reaffirmed 4/09

Lactose Intolerance in Infants, Children, and Adolescents (Clinical Report), 9/06, reaffirmed 8/12

Optimizing Bone Health in Children and Adolescents (Clinical Report), 9/14

Organic Foods: Health and Environmental Advantages and Disadvantages (Clinical Report) (joint with Council on Environmental Health), 10/12

Prevention of Pediatric Overweight and Obesity, 8/03, reaffirmed 10/06

Probiotics and Prebiotics in Pediatrics (Clinical Report) (joint with Section on Gastroenterology, Hepatology, and Nutrition), 11/10

Reimbursement for Foods for Special Dietary Use, 5/03, reaffirmed 1/06

Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate? (Clinical Report) (joint with Council on Sports Medicine and Fitness), 5/11

The Use and Misuse of Fruit Juice in Pediatrics, 5/01, reaffirmed 10/06, 8/13

Use of Soy Protein-Based Formulas in Infant Feeding (Clinical Report), 5/08

COMMITTEE ON PEDIATRIC AIDS

Adolescents and HIV Infection: The Pediatrician's Role in Promoting Routine Testing, 10/11

Adolescents and Human Immunodeficiency Virus Infection: The Role of the Pediatrician in Prevention and Intervention (joint with Committee on Adolescence), 1/01, reaffirmed 10/03, 1/05

Diagnosis of HIV-1 Infection in Children Younger Than 18 Months in the United States (Technical Report), 12/07, reaffirmed 4/10

Disclosure of Illness Status to Children and Adolescents With HIV Infection, 1/99, reaffirmed 2/02, 5/05, 1/09, 1/12

Education of Children With Human Immunodeficiency Virus Infection, 6/00, reaffirmed 3/03, 10/06, 4/10, 3/13

Evaluation and Management of the Infant Exposed to HIV-1 in the United States (Clinical Report), 12/08

HIV Testing and Prophylaxis to Prevent Mother-to-Child Transmission in the United States, 11/08, reaffirmed 6/11

Human Immunodeficiency Virus Screening (joint with Committee on Fetus and Newborn and American College of Obstetricians and Gynecologists), 7/99, reaffirmed 6/02, 5/05, 10/08, 5/12

Human Milk, Breastfeeding, and Transmission of Human Immunodeficiency Virus in the United States, 11/95, reaffirmed 11/99, 11/03, 2/08

Human Milk, Breastfeeding, and Transmission of Human Immunodeficiency Virus Type 1 in the United States (Technical Report), 11/03, reaffirmed 1/07

Identification and Care of HIV-Exposed and HIV-Infected Infants, Children, and Adolescents in Foster Care, 7/00, reaffirmed 3/03, 2/08, 6/11

Increasing Antiretroviral Drug Access for Children With HIV Infection (joint with Section on International Child Health), 4/07, reaffirmed 4/10

Infant Feeding and Transmission of Human Immunodeficiency Virus in the United States, 1/13

Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus (Clinical Report), 6/03, reaffirmed 1/07, 10/08

Psychosocial Support for Youth Living With HIV (Clinical Report), 2/14

Reducing the Risk of HIV Infection Associated With Illicit Drug Use, 2/06, reaffirmed 5/09, 5/12

Surveillance of Pediatric HIV Infection, 2/98, reaffirmed 2/02, 1/06, 1/11

Transitioning HIV-Infected Youth Into Adult Health Care, 6/13

COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE

Access to Optimal Emergency Care for Children, 1/07, reaffirmed 8/10, 7/14

Consent for Emergency Medical Services for Children and Adolescents (joint with Committee on Bioethics), 7/11

Death of a Child in the Emergency Department (joint with American College of Emergency Physicians and Emergency Nurses Association), 6/14

Death of a Child in the Emergency Department (Technical Report) (joint with American College of Emergency Physicians and Emergency Nurses Association), 6/14

Dispensing Medications at the Hospital Upon Discharge From an Emergency Department (Technical Report), 1/12

Emergency Information Forms and Emergency Preparedness for Children With Special Health Care Needs (joint with Council on Clinical Information Technology and American College of Emergency Physicians Pediatric Emergency Medicine Committee), 3/10, reaffirmed 7/14

Guidelines for Care of Children in the Emergency Department (joint with American College of Emergency Physicians and Emergency Nurses Association), 9/09, reaffirmed 4/13

Management of Pediatric Trauma (joint with Section on Orthopaedics, Section on Critical Care, Section on Surgery, Section on Transport Medicine, and Pediatric Orthopaedic Society of North America), 4/08, reaffirmed 4/13

Overcrowding Crisis in Our Nation's Emergency Departments: Is Our Safety Net Unraveling?, 9/04, reaffirmed 5/07, 6/11

Patient- and Family-Centered Care and the Role of the Emergency Physician Providing Care to a Child in the Emergency Department (joint with American College of Emergency Physicians), 11/06, reaffirmed 6/09, 10/11

Patient- and Family-Centered Care of Children in the Emergency Department (Technical Report), 8/08

Patient Safety in the Pediatric Emergency Care Setting, 12/07, reaffirmed 6/11, 7/14

Pediatric and Adolescent Mental Health Emergencies in the Emergency Medical Services System (Technical Report), 4/11, 7/14

Pediatric Care Recommendations for Freestanding Urgent Care Facilities, 4/14

Pediatric Mental Health Emergencies in the Emergency Medical Services System (joint with American College of Emergency Physicians), 10/06, reaffirmed 6/09, 4/13

Pediatric Observation Units (Clinical Report) (joint with Committee on Hospital Care), 6/12

The Pediatrician and Disaster Preparedness (joint with Committee on Medical Liability and Task Force on Terrorism), 2/06, reaffirmed 6/09, 9/13

Preparation for Emergencies in the Offices of Pediatricians and Pediatric Primary Care Providers, 7/07, reaffirmed 6/11

Relief of Pain and Anxiety in Pediatric Patients in Emergency Medical Systems (Clinical Report) (joint with Section on Anesthesiology and Pain Medicine), 10/12

Role of Pediatricians in Advocating Life Support Training Courses for Parents and the Public, 12/04, reaffirmed 5/07, 8/10, 8/13

Role of Pediatricians in Advocating Life Support Training Courses for Parents and the Public (Technical Report), 12/04, reaffirmed 5/07, 8/10, reaffirmed 1/14

The Role of the Pediatrician in Rural Emergency Medical Services for Children, 10/12

Ventricular Fibrillation and the Use of Automated External Defibrillators on Children (joint with Section on Cardiology and Cardiac Surgery), 11/07, reaffirmed 6/11, 7/14

Withholding or Termination of Resuscitation in Pediatric Out-of-Hospital Traumatic Cardiopulmonary Arrest (joint with American College of Surgeons and National Association of EMS Physicians), 3/14

COMMITTEE ON PEDIATRIC RESEARCH

Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations (Clinical Report) (joint with Committee on Drugs), 3/10, reaffirmed 1/14

Human Embryonic Stem Cell (hESC) and Human Embryo Research (joint with Committee on Bioethics), 10/12

Promoting Education, Mentorship, and Support for Pediatric Research, 4/14

Race/Ethnicity, Gender, Socioeconomic Status—Research Exploring Their Effects on Child Health: A Subject Review (Clinical Report), 6/00, reaffirmed 10/05, 1/09

Racial and Ethnic Disparities in the Health and Health Care of Children (Technical Report), 3/10, reaffirmed 5/13

COMMITTEE ON PEDIATRIC WORKFORCE

Enhancing Pediatric Workforce Diversity and Providing Culturally Effective Pediatric Care: Implications for Practice, Education, and Policy Making, 9/13

Financing Graduate Medical Education to Meet the Needs of Children and the Future Pediatrician Workforce, 4/08, reaffirmed 1/12

Nondiscrimination in Pediatric Health Care, 10/07, reaffirmed 6/11

Pediatric Primary Health Care, 1/11, reaffirmed 10/13

The Pediatrician Workforce: Current Status and Future Prospects (Technical Report), 7/05

Pediatrician Workforce Policy Statement, 7/13

Prevention of Sexual Harassment in the Workplace and Educational Settings, 10/06, reaffirmed 5/09, 1/12

Scope of Practice Issues in the Delivery of Pediatric Health Care, 5/13

COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE

2014 Recommendations for Pediatric Preventive Health Care (joint with Bright Futures Periodicity Schedule Workgroup), 2/14

AAP Principles Concerning Retail-Based Clinics, 2/14

Eye Examination in Infants, Children, and Young Adults by Pediatricians (joint with Section on Ophthalmology, American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology), 4/03, reaffirmed 5/07

Hearing Assessment in Infants and Children: Recommendations Beyond Neonatal Screening (Clinical Report) (joint with Section on Otolaryngology–Head and Neck Surgery), 9/09

Immunization Information Systems, 9/06, reaffirmed 10/11

Immunizing Parents and Other Close Family Contacts in the Pediatric Office Setting (Technical Report) (joint with Committee on Infectious Diseases), 12/11

Increasing Immunization Coverage (joint with Council on Community Pediatrics), 5/10

Instrument-Based Pediatric Vision Screening Policy Statement (joint with Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 10/12

Physician Health and Wellness (Clinical Report) (joint with Section on Integrative Medicine), 9/14

Prevention and Management of Positional Skull Deformities in Infants (Clinical Report) (joint with Section on Neurological Surgery), 11/11

Principles for the Development and Use of Quality Measures (joint with Steering Committee on Quality Improvement and Management), 2/08

Recommendations for Preventive Pediatric Health Care (joint with Bright Futures Steering Committee), 12/07, reaffirmed 1/11

Use of Chaperones During the Physical Examination of the Pediatric Patient, 4/11

COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH

Coparent or Second-Parent Adoption by Same-Sex Parents, 2/02, reaffirmed 5/09

Coparent or Second-Parent Adoption by Same-Sex Parents (Technical Report), 2/02, reaffirmed 5/09

Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health (joint with Committee on Early Childhood, Adoption, and Dependent Care and Section on Developmental and Behavioral Pediatrics), 12/11

Fathers and Pediatricians: Enhancing Men's Roles in the Care and Development of Their Children (Clinical Report), 5/04, reaffirmed 8/13

The Future of Pediatrics: Mental Health Competencies for Pediatric Primary Care (joint with Task Force on Mental Health), 6/09, reaffirmed 8/13

Guidance for Effective Discipline, 4/98, reaffirmed 3/01, 1/05, 5/12, 4/14

Health and Mental Health Needs of Children in US Military Families (Clinical Report) (joint with Section on Uniformed Services), 5/13

Helping Children and Families Deal With Divorce and Separation (Clinical Report), 11/02, reaffirmed 1/06

The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bonds (Clinical Report) (joint with Committee on Communications), 1/07

The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bond: Focus on Children in Poverty (Clinical Report) (joint with Council on Communications and Media), 12/11

Incorporating Recognition and Management of Perinatal and Postpartum Depression Into Pediatric Practice (Clinical Report), 10/10

The Lifelong Effects of Early Childhood Adversity and Toxic Stress (Technical Report) (joint with Committee on Early Childhood, Adoption, and Dependent Care and Section on Developmental and Behavioral Pediatrics), 12/11

The New Morbidity Revisited: A Renewed Commitment to the Psychosocial Aspects of Pediatric Care, 11/01

The Pediatrician and Childhood Bereavement, 2/00, reaffirmed 1/04, 3/13

The Pediatrician's Role in the Prevention of Missing Children (Clinical Report), 10/04

The Prenatal Visit (Clinical Report), 9/09, reaffirmed 5/14

Promoting the Well-Being of Children Whose Parents Are Gay or Lesbian, 3/13

Promoting the Well-Being of Children Whose Parents Are Gay or Lesbian (Technical Report), 3/13

Psychosocial Implications of Disaster or Terrorism on Children: A Guide for the Pediatrician (Clinical Report) (joint with Task Force on Terrorism), 9/05

Psychosocial Risks of Chronic Health Conditions in Childhood and Adolescence (joint with Committee on Children With Disabilities), 12/93, reaffirmed 10/96

Sexuality Education for Children and Adolescents (joint with Committee on Adolescence), 8/01, reaffirmed 10/04

Supporting the Family After the Death of a Child (Clinical Report), 11/12

COMMITTEE ON SUBSTANCE ABUSE

Alcohol Use by Youth and Adolescents: A Pediatric Concern, 4/10

Attention-Deficit/Hyperactivity Disorder and Substance Abuse (Clinical Report), 6/14

Improving Substance Abuse Prevention, Assessment, and Treatment Financing for Children and Adolescents (joint with Committee on Child Health Financing), 10/01

Indications for Management and Referral of Patients Involved in Substance Abuse, 7/00

Inhalant Abuse (Clinical Report) (joint with Committee on Native American Child Health), 5/07

Legalization of Marijuana: Potential Impact on Youth (joint with Committee on Adolescence), 6/04

Legalization of Marijuana: Potential Impact on Youth (Technical Report) (joint with Committee on Adolescence), 6/04

Marijuana: A Continuing Concern for Pediatricians, 10/99, reaffirmed 4/03

Prenatal Substance Abuse: Short- and Long-term Effects on the Exposed Fetus (Technical Report) (joint with Committee on Fetus and Newborn), 2/13

The Role of Schools in Combating Illicit Substance Abuse (joint with Council on School Health), 12/07

Substance Use Screening, Brief Intervention, and Referral to Treatment for Pediatricians, 10/11

Testing for Drugs of Abuse in Children and Adolescents (Clinical Report), 5/14

Tobacco, Alcohol, and Other Drugs: The Role of the Pediatrician in Prevention, Identification, and Management of Substance Abuse (Clinical Report), 3/05, reaffirmed 3/13

Tobacco as a Substance of Abuse (Technical Report), 10/09

Tobacco Use: A Pediatric Disease (joint with Committee on Environmental Health, Committee on Adolescence, and Committee on Native American Child Health), 10/09, reaffirmed 5/13

COUNCIL ON CHILDREN WITH DISABILITIES (FORMERLY COMMITTEE ON CHILDREN WITH DISABILITIES AND SECTION ON CHILDREN WITH DISABILITIES)

Auditory Integration Training and Facilitated Communication for Autism, 8/98, reaffirmed 5/02, 1/06, 12/09

Care Coordination in the Medical Home: Integrating Health and Related Systems of Care for Children With Special Health Care Needs, 11/05

Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness or Disability, 3/01, reaffirmed 1/05, 5/10

Early Intervention, IDEA Part C Services, and the Medical Home: Collaboration for Best Practice and Best Outcomes (Clinical Report), 9/13

Guidelines for Home Care of Infants, Children, and Adolescents With Chronic Disease, 7/95, reaffirmed 4/00, 1/06

Home Care of Children and Youth With Complex Health Care Needs and Technology Dependencies (Clinical Report), 4/12

Identification and Evaluation of Children With Autism Spectrum Disorders (Clinical Report), 11/07, reaffirmed 9/10, 8/14

Identifying Infants and Young Children With Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening (joint with Section on Developmental and Behavioral Pediatrics, Bright Futures Steering Committee, and Medical Home Initiatives for Children With Special Needs Project Advisory Committee), 7/06, reaffirmed 12/09, 8/14

Learning Disabilities, Dyslexia, and Vision (joint with Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 7/09, reaffirmed 7/14

Learning Disabilities, Dyslexia, and Vision (Technical Report) (joint with Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 3/11

Maltreatment of Children With Disabilities (Clinical Report) (joint with Committee on Child Abuse and Neglect), 5/07, reaffirmed 1/11

Management of Children With Autism Spectrum Disorders (Clinical Report), 11/07, reaffirmed 9/10, 8/14

Nonoral Feeding for Children and Youth With Developmental or Acquired Disabilities (Clinical Report), 11/14

Oral Health Care for Children With Developmental Disabilities (Clinical Report) (joint with Section on Oral Health), 2/13

Out-of-Home Placement for Children and Adolescents With Disabilities (Clinical Report), 9/14

Parent-Provider-Community Partnerships: Optimizing Outcomes for Children With Disabilities (Clinical Report), 9/11

Patient- and Family-Centered Care Coordination: A Framework for Integrating Care for Children and Youth Across Multiple Systems (joint with Medical Home Implementation Project Advisory Committee), 4/14

The Pediatrician's Role in Development and Implementation of an Individual Education Plan (IEP) and/or an Individual Family Service Plan (IFSP), 7/99, reaffirmed 11/02, 1/06

Prescribing Assistive-Technology Systems: Focus on Children With Impaired Communication (Clinical Report), 6/08, reaffirmed 1/12

Prescribing Therapy Services for Children With Motor Disabilities (Clinical Report), 6/04, reaffirmed 5/07, 5/11

Promoting the Participation of Children With Disabilities in Sports, Recreation, and Physical Activities (Clinical Report), 5/08, reaffirmed 1/12

Providing a Primary Care Medical Home for Children and Youth With Cerebral Palsy (Clinical Report), 10/11

Providing a Primary Care Medical Home for Children and Youth With Spina Bifida (Clinical Report), 11/11

Provision of Educationally Related Services for Children and Adolescents With Chronic Diseases and Disabling Conditions, 6/07

Psychosocial Risks of Chronic Health Conditions in Childhood and Adolescence (joint with Committee on Psychosocial Aspects of Child and Family Health), 12/93, reaffirmed 10/96

Role of the Medical Home in Family-Centered Early Intervention Services, 11/07

Sensory Integration Therapies for Children With Developmental and Behavioral Disorders (joint with Section on Complementary and Integrative Medicine), 5/12

Sexuality of Children and Adolescents With Developmental Disabilities (Clinical Report), 7/06, reaffirmed 12/09, 7/13

Supplemental Security Income (SSI) for Children and Youth With Disabilities, 11/09

The Treatment of Neurologically Impaired Children Using Patterning, 11/99, reaffirmed 11/02, 1/06, 8/10, 4/14

COUNCIL ON CLINICAL INFORMATION TECHNOLOGY (FORMERLY STEERING COMMITTEE ON CLINICAL INFORMATION TECHNOLOGY, SECTION ON COMPUTERS AND OTHER TECHNOLOGIES, AND TASK FORCE ON MEDICAL INFORMATICS)

Electronic Prescribing Systems in Pediatrics: The Rationale and Functionality Requirements, 6/07

Electronic Prescribing Systems in Pediatrics: The Rationale and Functionality Requirements (Technical Report), 6/07

Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management, 3/13

Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management (Technical Report), 3/13

Emergency Information Forms and Emergency Preparedness for Children With Special Health Care Needs (joint with Committee on Pediatric Emergency Medicine and American College of Emergency Physicians Pediatric Emergency Medicine Committee), 3/10, reaffirmed 7/14

Health Information Technology and the Medical Home, 4/11

Pediatric Aspects of Inpatient Health Information Technology Systems (Technical Report), 12/08

Special Requirements of Electronic Health Record Systems in Pediatrics (Clinical Report), 3/07, reaffirmed 5/12

Standards for Health Information Technology to Ensure Adolescent Privacy (joint with Committee on Adolescence), 10/12

COUNCIL ON COMMUNICATIONS AND MEDIA (FORMERLY COMMITTEE ON COMMUNICATIONS AND COMMITTEE ON PUBLIC EDUCATION)

Children, Adolescents, and Advertising, 12/06, reaffirmed 3/10

Children, Adolescents, and Television, 2/01

Children, Adolescents, and the Media, 10/13

Children, Adolescents, Obesity, and the Media, 7/11

Children, Adolescents, Substance Abuse, and the Media, 9/10

Impact of Music, Music Lyrics, and Music Videos on Children and Youth, 10/09

The Impact of Social Media on Children, Adolescents, and Families (Clinical Report), 3/11

The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bonds (Clinical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health), 1/07

The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bond: Focus on Children in Poverty (Clinical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health), 12/11

Media Education, 9/10

Media Use by Children Younger Than 2 Years, 10/11

Media Violence, 10/09

Sexuality, Contraception, and the Media, 8/10

COUNCIL ON COMMUNITY PEDIATRICS (FORMERLY COMMITTEE ON COMMUNITY HEALTH SERVICES)

Child Fatality Review (joint with Committee on Child Abuse and Neglect and Committee on Injury, Violence, and Poison Prevention), 8/10, reaffirmed 5/14

Community Pediatrics: Navigating the Intersection of Medicine, Public Health, and Social Determinants of Children's Health, 2/13

Ethical Considerations in Research With Socially Identifiable Populations (joint with Committee on Native American Child Health), 1/04, reaffirmed 10/07, 1/13

Health Equity and Children's Rights (joint with Committee on Native American Child Health), 3/10, reaffirmed 10/13

Increasing Immunization Coverage (joint with Committee on Practice and Ambulatory Medicine), 5/10

The Pediatrician's Role in Community Pediatrics, 4/05, reaffirmed 1/10

Prevention of Agricultural Injuries Among Children and Adolescents (joint with Committee on Injury and Poison Prevention), 10/01, reaffirmed 1/07, 11/11

Providing Care for Children and Adolescents Facing Homelessness and Housing Insecurity, 5/13

Providing Care for Immigrant, Migrant, and Border Children, 5/13

The Role of Preschool Home-Visiting Programs in Improving Children's Developmental and Health Outcomes, 1/09

COUNCIL ON EARLY CHILDHOOD (FORMERLY COMMITTEE ON EARLY CHILDHOOD, ADOPTION, AND DEPENDENT CARE AND COMMITTEE ON EARLY CHILDHOOD)

Care of Adolescent Parents and Their Children (Clinical Report) (joint with Committee on Adolescence), 11/12

Comprehensive Health Evaluation of the Newly Adopted Child (Clinical Report), 12/11

Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health (joint with Committee on Psychosocial Aspects of Child and Family Health and Section on Developmental and Behavioral Pediatrics), 12/11

Families and Adoption: The Pediatrician's Role in Supporting Communication (Clinical Report), 12/03

Health Care of Youth Aging Out of Foster Care (joint with Council on Foster Care, Adoption, and Kinship Care), 11/12

The Inappropriate Use of School "Readiness" Tests (joint with Committee on School Health), 3/95, reaffirmed 4/98, 1/04, 4/10

The Lifelong Effects of Early Childhood Adversity and Toxic Stress (Technical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health and Section on Developmental and Behavioral Pediatrics), 12/11

Literacy Promotion: An Essential Component of Primary Care Pediatric Practice, 7/14

Parental Leave for Residents and Pediatric Training Programs (joint with Section on Medical Students, Residents, and Fellowship Trainees), 1/13

The Pediatrician's Role in Family Support and Family Support Programs, 11/11

The Pediatrician's Role in Supporting Adoptive Families (Clinical Report) (joint with Council on Foster Care, Adoption, and Kinship Care), 9/12

Quality Early Education and Child Care From Birth to Kindergarten, 1/05, reaffirmed 12/09

School Readiness (Technical Report) (joint with Council on School Health), 4/08, reaffirmed 9/13

Selecting Appropriate Toys for Young Children: The Pediatrician's Role (Clinical Report), 4/03, reaffirmed 10/06, 5/11

COUNCIL ON ENVIRONMENTAL HEALTH (FORMERLY COMMITTEE ON ENVIRONMENTAL HEALTH)

Ambient Air Pollution: Health Hazards to Children, 12/04, reaffirmed 4/09

The Built Environment: Designing Communities to Promote Physical Activity in Children, 5/09, reaffirmed 1/13

Chemical-Biological Terrorism and Its Impact on Children (joint with Committee on Infectious Diseases), 9/06, reaffirmed 1/11

Chemical-Management Policy: Prioritizing Children's Health, 4/11

Drinking Water From Private Wells and Risks to Children (joint with Committee on Infectious Diseases), 5/09, reaffirmed 1/13

Drinking Water From Private Wells and Risks to Children (Technical Report) (joint with Committee on Infectious Diseases), 5/09, reaffirmed 1/13

Global Climate Change and Children's Health, 11/07, reaffirmed 5/12

Global Climate Change and Children's Health (Technical Report), 11/07, reaffirmed 5/12

Infant Methemoglobinemia: The Role of Dietary Nitrate in Food and Water (Clinical Report) (joint with Committee on Nutrition), 9/05, reaffirmed 4/09

Iodine Deficiency, Pollutant Chemicals, and the Thyroid: New Information on an Old Problem, 5/14

Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics (Technical Report) (joint with Committee on Infectious Diseases), 9/04, reaffirmed 10/08, 4/13

Organic Foods: Health and Environmental Advantages and Disadvantages (Clinical Report) (joint with Committee on Nutrition), 10/12

Pesticide Exposure in Children, 11/12

Pesticide Exposure in Children (Technical Report), 11/12

Radiation Disasters and Children, 6/03, reaffirmed 1/07

Secondhand and Prenatal Tobacco Smoke Exposure (Technical Report) (joint with Committee on Native American Child Health and Committee on Adolescence), 10/09, reaffirmed 5/14

Spectrum of Noninfectious Health Effects From Molds, 12/06, reaffirmed 1/11

Spectrum of Noninfectious Health Effects From Molds (Technical Report), 12/06, reaffirmed 1/11

Tobacco Use: A Pediatric Disease (joint with Committee on Substance Abuse, Committee on Adolescence, and Committee on Native American Child Health), 10/09, reaffirmed 5/13

Ultraviolet Radiation: A Hazard to Children and Adolescents (joint with Section on Dermatology), 2/11

Ultraviolet Radiation: A Hazard to Children and Adolescents (Technical Report) (joint with Section on Dermatology), 3/11

COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE (FORMER SECTION ON ADOPTION AND FOSTER CARE, TASK FORCE ON FOSTER CARE, AND COMMITTEE ON EARLY CHILDHOOD, ADOPTION, AND DEPENDENT CARE)

Health Care of Youth Aging Out of Foster Care (joint with Committee on Early Childhood), 11/12

The Pediatrician's Role in Supporting Adoptive Families (Clinical Report) (joint with Committee on Early Childhood), 9/12

Understanding the Behavioral and Emotional Consequences of Child Abuse (Clinical Report) (joint with Committee on Child Abuse and Neglect, American Academy of Child and Adolescent Psychiatry, and National Center for Child Traumatic Stress), 9/08, reaffirmed 8/12

COUNCIL ON INJURY, VIOLENCE, AND POISON PREVENTION (FORMER COMMITTEE ON INJURY, VIOLENCE, AND POISON PREVENTION)

All-Terrain Vehicle Injury Prevention: Two-, Three-, and Four-Wheeled Unlicensed Motor Vehicles, 6/00, reaffirmed 5/04, 1/07, 5/13

Bicycle Helmets, 10/01, reaffirmed 1/05, 2/08, 11/11

Child Fatality Review (joint with Committee on Child Abuse and Neglect and Council on Community Pediatrics), 8/10, reaffirmed 5/14

Child Passenger Safety, 3/11

Child Passenger Safety (Technical Report), 3/11

Children in Pickup Trucks, 10/00, reaffirmed 5/04, 1/07

Falls From Heights: Windows, Roofs, and Balconies, 5/01, reaffirmed 10/04, 5/07, 6/10

Firearm-Related Injuries Affecting the Pediatric Population, 10/12

Fireworks-Related Injuries to Children, 7/01, reaffirmed 1/05, 2/08, 10/11

The Hospital Record of the Injured Child and the Need for External Cause-of-Injury Codes, 2/99, reaffirmed 5/02, 5/05, 10/08, 10/13

Injuries Associated With Infant Walkers, 9/01, reaffirmed 1/05, 2/08, 10/11

Injury Risk of Nonpowder Guns (Technical Report), 11/04, reaffirmed 2/08, 10/11

In-line Skating Injuries in Children and Adolescents (joint with Committee on Sports Medicine and Fitness), 4/98, reaffirmed 1/02, 1/06, 1/09, 11/11

Intimate Partner Violence: The Role of the Pediatrician (Clinical Report) (joint with Committee on Child Abuse and Neglect), 4/10, reaffirmed 1/14

Lawn Mower-Related Injuries to Children, 6/01, reaffirmed 10/04, 5/07, 6/10

Lawn Mower-Related Injuries to Children (Technical Report), 6/01, reaffirmed 10/04, 5/07, 6/10

Office-Based Counseling for Unintentional Injury Prevention (Clinical Report), 1/07

Pedestrian Safety, 7/09, reaffirmed 8/13

Personal Watercraft Use by Children and Adolescents, 2/00, reaffirmed 5/04, 1/07, 6/10

Prevention of Agricultural Injuries Among Children and Adolescents (joint with Committee on Community Health Services), 10/01, reaffirmed 1/07, 11/11

Prevention of Choking Among Children, 2/10

Prevention of Drowning, 5/10

Prevention of Drowning (Technical Report), 5/10

The Prevention of Unintentional Injury Among American Indian and Alaska Native Children: A Subject Review (Clinical Report) (joint with Committee on Native American Child Health), 12/99, reaffirmed 12/02, 1/06, 1/09

Reducing the Number of Deaths and Injuries From Residential Fires, 6/00

Restraint Use on Aircraft, 11/01, reaffirmed 5/05, 10/08

Role of the Pediatrician in Youth Violence Prevention, 6/09

Safe Transportation of Newborns at Hospital Discharge, 10/99, reaffirmed 1/03, 1/06, 10/08

Safe Transportation of Preterm and Low Birth Weight Infants at Hospital Discharge (Clinical Report) (joint with Committee on Fetus and Newborn), 4/09, reaffirmed 8/13

School Bus Transportation of Children With Special Health Care Needs, 8/01, reaffirmed 1/05, 2/08, 5/13

School Transportation Safety (joint with Council on School Health), 7/07, reaffirmed 10/11

Shopping Cart–Related Injuries to Children, 8/06, reaffirmed 4/09, 8/13

Shopping Cart–Related Injuries to Children (Technical Report), 8/06, reaffirmed 4/09, 8/13

Skateboard and Scooter Injuries, 3/02, reaffirmed 5/05, 10/08, 10/13

Snowmobiling Hazards, 11/00, reaffirmed 5/04, 1/07, 6/10

Swimming Programs for Infants and Toddlers (joint with Committee on Sports Medicine and Fitness), 4/00, reaffirmed 5/04

The Teen Driver (joint with Committee on Adolescence), 12/06, reaffirmed 6/10

Transporting Children With Special Health Care Needs, 10/99, reaffirmed 1/03, 1/06, 3/13

COUNCIL ON SCHOOL HEALTH (FORMERLY COMMITTEE ON SCHOOL HEALTH AND SECTION ON SCHOOL HEALTH)

Active Healthy Living: Prevention of Childhood Obesity Through Increased Physical Activity (joint with Council on Sports Medicine and Fitness), 5/06, reaffirmed 5/09, 8/12

Climatic Heat Stress and Exercising Children and Adolescents (joint with Council on Sports Medicine and Fitness), 8/11

Corporal Punishment in Schools, 8/00, reaffirmed 6/03, 5/06, 2/12

Creating Healthy Camp Experiences, 3/11

The Crucial Role of Recess in School, 12/12

Disaster Planning for Schools, 10/08, reaffirmed 9/11

Guidance for the Administration of Medication in School, 9/09, reaffirmed 2/13

Head Lice (Clinical Report) (joint with Committee on Infectious Diseases), 7/10

Home, Hospital, and Other Non–School-based Instruction for Children and Adolescents Who Are Medically Unable to Attend School, 11/00, reaffirmed 6/03, 5/06

Honoring Do-Not-Attempt-Resuscitation Requests in Schools (joint with Committee on Bioethics), 4/10, reaffirmed 7/13

The Inappropriate Use of School “Readiness” Tests (joint with Committee on Early Childhood, Adoption, and Dependent Care), 3/95, reaffirmed 4/98, 1/04, 4/10

Medical Emergencies Occurring at School, 10/08, reaffirmed 9/11

Organized Sports for Children and Preadolescents (joint with Committee on Sports Medicine and Fitness), 6/01, reaffirmed 1/05, 6/11

Out-of-School Suspension and Expulsion, 2/13

Preventing and Treating Homesickness (Clinical Report), 1/07, reaffirmed 5/12

Returning to Learning Following a Concussion (Clinical Report) (joint with Council on Sports Medicine and Fitness), 10/13

The Role of Schools in Combating Illicit Substance Abuse (joint with Committee on Substance Abuse), 12/07

Role of the School Nurse in Providing School Health Services, 5/08

Role of the School Physician, 12/12

School Health Assessments, 4/00, reaffirmed 6/03, 5/06, 10/11

School Health Centers and Other Integrated School Health Services, 1/01

School Readiness (Technical Report) (joint with Committee on Early Childhood, Adoption, and Dependent Care), 4/08, reaffirmed 9/13

School Start Times for Adolescents (joint with Adolescent Sleep Working Group and Committee on Adolescence), 8/14

School Transportation Safety (joint with Committee on Injury, Violence, and Poison Prevention), 7/07, reaffirmed 10/11

School-Based Health Centers and Pediatric Practice, 1/12

School-Based Mental Health Services, 6/04, reaffirmed 5/09

Soft Drinks in Schools, 1/04, reaffirmed 1/09

COUNCIL ON SPORTS MEDICINE AND FITNESS (FORMERLY COMMITTEE ON SPORTS MEDICINE AND FITNESS AND SECTION ON SPORTS MEDICINE AND FITNESS)

Active Healthy Living: Prevention of Childhood Obesity Through Increased Physical Activity (joint with Council on School Health), 5/06, reaffirmed 5/09, 8/12

Anterior Cruciate Ligament Injuries: Diagnosis, Treatment, and Prevention (Clinical Report) (joint with Section on Orthopaedics), 4/14

Athletic Participation by Children and Adolescents Who Have Systemic Hypertension, 5/10, reaffirmed 5/13

Baseball and Softball, 2/12

Boxing Participation by Children and Adolescents (joint with Canadian Paediatric Society), 8/11

Cheerleading Injuries: Epidemiology and Recommendations for Prevention, 10/12

Climatic Heat Stress and Exercising Children and Adolescents (joint with Council on School Health), 8/11

Human Immunodeficiency Virus and Other Blood-borne Viral Pathogens in the Athletic Setting, 12/99, reaffirmed 1/05, 1/09, 11/11

Injuries in Youth Soccer (Clinical Report), 1/10, reaffirmed 5/13

In-line Skating Injuries in Children and Adolescents (joint with Committee on Injury and Poison Prevention), 4/98, reaffirmed 1/02, 1/06, 1/09, 11/11

Intensive Training and Sports Specialization in Young Athletes, 7/00, reaffirmed 11/04, 1/06, 5/09

Medical Concerns in the Female Athlete, 9/00, reaffirmed 5/05, 5/08

Medical Conditions Affecting Sports Participation (Clinical Report), 4/08, reaffirmed 5/11, 6/14

Organized Sports for Children and Preadolescents (joint with Committee on School Health), 6/01, reaffirmed 1/05, 6/11

Overuse Injuries, Overtraining, and Burnout in Child and Adolescent Athletes (Clinical Report), 6/07, reaffirmed 3/11, 6/14

Promotion of Healthy Weight-Control Practices in Young Athletes, 12/05

Protective Eyewear for Young Athletes (joint with American Academy of Ophthalmology), 3/04, reaffirmed 2/08, 6/11

Reducing Injury Risk From Body Checking in Boys' Youth Ice Hockey, 5/14

Returning to Learning Following a Concussion (Clinical Report) (joint with Council on School Health), 10/13

Sport-Related Concussion in Children and Adolescents (Clinical Report), 8/10, reaffirmed 8/14

Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate? (Clinical Report) (joint with Committee on Nutrition), 5/11

Strength Training by Children and Adolescents, 4/08, reaffirmed 6/11

Swimming Programs for Infants and Toddlers (joint with Committee on Injury and Poison Prevention), 4/00, reaffirmed 5/04

Trampoline Safety in Childhood and Adolescence, 9/12

Use of Performance-Enhancing Substances, 4/05, reaffirmed 5/08

DISASTER PREPAREDNESS ADVISORY COUNCIL

Pediatric Anthrax Clinical Management (Clinical Report) (joint with Committee on Infectious Diseases), 4/14

Pediatric Anthrax Clinical Management: Executive Summary (Clinical Report) (joint with Committee on Infectious Diseases), 4/14

JOINT COMMITTEE ON INFANT HEARING

Supplement to the JCIH 2007 Position Statement: Principles and Guidelines for Early Intervention After Confirmation That a Child Is Deaf or Hard of Hearing, 3/13

Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs, 10/07

MEDICAL HOME IMPLEMENTATION PROJECT ADVISORY COMMITTEE

Patient- and Family-Centered Care Coordination: A Framework for Integrating Care for Children and Youth Across Multiple Systems (joint with Council on Children With Disabilities), 4/14

MEDICAL HOME INITIATIVES FOR CHILDREN WITH SPECIAL NEEDS PROJECT ADVISORY COMMITTEE

Identifying Infants and Young Children With Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening (joint with Council on Children With Disabilities, Section on Developmental and Behavioral Pediatrics, and Bright Futures Steering Committee), 7/06, reaffirmed 12/09, 8/14

The Medical Home, 7/02, reaffirmed 5/08

NEUROMOTOR SCREENING EXPERT PANEL

Motor Delays: Early Identification and Evaluation (Clinical Report), 5/13

NEWBORN SCREENING AUTHORIZING COMMITTEE

Newborn Screening Expands: Recommendations for Pediatricians and Medical Homes—Implications for the System (Clinical Report), 1/08

RETAIL-BASED CLINIC POLICY WORK GROUP

AAP Principles Concerning Retail-Based Clinics, 12/06, reaffirmed 1/11

SECTION ON ALLERGY AND IMMUNOLOGY

Allergy Testing in Childhood: Using Allergen-Specific IgE Tests (Clinical Report), 12/11

Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The Role of Maternal Dietary Restriction, Breastfeeding, Timing of Introduction of Complementary Foods, and Hydrolyzed Formulas (Clinical Report) (joint with Committee on Nutrition), 1/08

Management of Food Allergy in the School Setting (Clinical Report), 11/10

Self-injectable Epinephrine for First-Aid Management of Anaphylaxis (Clinical Report), 3/07

SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE

Do-Not-Resuscitate Orders for Pediatric Patients Who Require Anesthesia and Surgery (Clinical Report) (joint with Section on Surgery and Committee on Bioethics), 12/04, reaffirmed 1/09, 10/12

The Pediatrician's Role in the Evaluation and Preparation of Pediatric Patients Undergoing Anesthesia, 8/14

Premedication for Nonemergency Endotracheal Intubation in the Neonate (Clinical Report) (joint with Committee on Fetus and Newborn), 2/10, reaffirmed 8/13

Recognition and Management of Iatrogenically Induced Opioid Dependence and Withdrawal in Children (Clinical Report) (joint with Committee on Drugs), 12/13

Relief of Pain and Anxiety in Pediatric Patients in Emergency Medical Systems (Clinical Report) (joint with Committee on Pediatric Emergency Medicine), 10/12

SECTION ON BREASTFEEDING

Breastfeeding and the Use of Human Milk, 2/12

WIC Program, 11/01

SECTION ON CARDIOLOGY AND CARDIAC SURGERY

ACCF/AHA/AAP Recommendations for Training in Pediatric Cardiology (joint with American College of Cardiology Foundation and American Heart Association), 12/05, reaffirmed 1/09

Cardiovascular Health Supervision for Individuals Affected by Duchenne or Becker Muscular Dystrophy (Clinical Report), 12/05, reaffirmed 1/09

Cardiovascular Monitoring and Stimulant Drugs for Attention-Deficit/Hyperactivity Disorder (joint with Black Box Working Group), 8/08

Echocardiography in Infants and Children, 6/97, reaffirmed 3/03, 3/07

Endorsement of Health and Human Services Recommendation for Pulse Oximetry Screening for Critical Congenital Heart Disease, 12/11

Guidelines for Pediatric Cardiovascular Centers, 3/02, reaffirmed 10/07

Pediatric Sudden Cardiac Arrest, 3/12

Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP (joint with Committee on Fetus and Newborn and American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research), 8/09

Ventricular Fibrillation and the Use of Automated External Defibrillators on Children (joint with Committee on Pediatric Emergency Medicine), 11/07, reaffirmed 6/11, 7/14

SECTION ON CLINICAL PHARMACOLOGY AND THERAPEUTICS

Fever and Antipyretic Use in Children (Clinical Report) (joint with Committee on Drugs), 2/11

SECTION ON COMPLEMENTARY AND INTEGRATIVE MEDICINE (FORMERLY PROVISIONAL SECTION ON COMPLEMENTARY, HOLISTIC, AND INTEGRATIVE MEDICINE)

Sensory Integration Therapies for Children With Developmental and Behavioral Disorders (joint with Council on Children With Disabilities), 5/12

The Use of Complementary and Alternative Medicine in Pediatrics (Clinical Report) (joint with Task Force on Complementary and Alternative Medicine), 12/08, reaffirmed 10/12, 1/13

SECTION ON CRITICAL CARE

Admission and Discharge Guidelines for the Pediatric Patient Requiring Intermediate Care (Clinical Report) (joint with Committee on Hospital Care and Society of Critical Care Medicine), 5/04, reaffirmed 2/08, 1/13

Guidelines for Developing Admission and Discharge Policies for the Pediatric Intensive Care Unit (joint with Committee on Hospital Care and Society of Critical Care Medicine), 4/99, reaffirmed 5/05, 2/08, 1/13

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations (Clinical Report) (joint with Section on Neurology, Society of Critical Care Medicine, and Child Neurology Society), 8/11

Management of Pediatric Trauma (joint with Section on Orthopaedics, Committee on Pediatric Emergency Medicine, Section on Surgery, Section on Transport Medicine, and Pediatric Orthopaedic Society of North America), 4/08, reaffirmed 4/13

Pediatric Organ Donation and Transplantation (joint with Committee on Hospital Care and Section on Surgery), 3/10, reaffirmed 3/14

SECTION ON DERMATOLOGY

Atopic Dermatitis: Skin-Directed Management (Clinical Report), 11/14

Ultraviolet Radiation: A Hazard to Children and Adolescents (joint with Council on Environmental Health), 2/11

Ultraviolet Radiation: A Hazard to Children and Adolescents (Technical Report) (joint with Council on Environmental Health), 3/11

SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS

Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health (joint with Committee on Psychosocial Aspects of Child and Family Health and Committee on Early Childhood, Adoption, and Dependent Care), 12/11

Identifying Infants and Young Children With Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening (joint with Council on Children With Disabilities, Bright Futures Steering Committee, and Medical Home Initiatives for Children With Special Needs Project Advisory Committee), 7/06, reaffirmed 12/09, 8/14

The Lifelong Effects of Early Childhood Adversity and Toxic Stress (Technical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health and Committee on Early Childhood, Adoption, and Dependent Care), 12/11

SECTION ON ENDOCRINOLOGY

Bone Densitometry in Children and Adolescents (Clinical Report), 12/10

Congenital Adrenal Hyperplasia (Technical Report) (joint with Committee on Genetics), 12/00, reaffirmed 10/04

Evaluating Children With Fractures for Child Physical Abuse (Clinical Report), (joint with Committee on Child Abuse and Neglect; Section on Radiology; Section on Orthopaedics; and Society for Pediatric Radiology), 1/14

Prevention and Treatment of Type 2 Diabetes Mellitus in Children, With Special Emphasis on American Indian and Alaska Native Children (Clinical Report) (joint with Committee on Native American Child Health), 10/03, reaffirmed 10/08

Screening for Retinopathy in the Pediatric Patient With Type 1 Diabetes Mellitus (Clinical Report) (joint with Section on Ophthalmology and American Association for Pediatric Ophthalmology and Strabismus), 7/05, reaffirmed 1/09, 7/14

Update of Newborn Screening and Therapy for Congenital Hypothyroidism (Clinical Report) (joint with Committee on Genetics, American Thyroid Association, and Lawson Wilkins Pediatric Endocrine Society), 6/06, reaffirmed 12/11

SECTION ON GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION

Gastroesophageal Reflux: Management Guidance for the Pediatrician (Clinical Report), 4/13

Probiotics and Prebiotics in Pediatrics (Clinical Report) (joint with Committee on Nutrition), 11/10

SECTION ON HEMATOLOGY/ONCOLOGY

Evaluating for Suspected Child Abuse: Conditions That Predispose to Bleeding (Technical Report) (joint with Committee on Child Abuse and Neglect), 3/13

Evaluation for Bleeding Disorders in Suspected Child Abuse (Clinical Report) (joint with Committee on Child Abuse and Neglect), 3/13

Guidelines for Pediatric Cancer Centers, 6/04, reaffirmed 10/08

Health Supervision for Children With Sickle Cell Disease (joint with Committee on Genetics), 3/02, reaffirmed 1/06, 1/11

Long-term Follow-up Care for Pediatric Cancer Survivors (Clinical Report) (joint with Children's Oncology Group), 3/09, reaffirmed 4/13

Preservation of Fertility in Pediatric and Adolescent Patients With Cancer (Technical Report) (joint with Committee on Bioethics and Section on Surgery), 5/08, reaffirmed 2/12

Standards for Pediatric Cancer Centers, 7/14

SECTION ON HOME CARE

Financing of Pediatric Home Health Care (joint with Committee on Child Health Financing), 8/06

SECTION ON HOSPICE AND PALLIATIVE MEDICINE

Pediatric Palliative Care and Hospice Care Commitments, Guidelines, and Recommendations (joint with Committee on Hospital Care), 10/13

SECTION ON HOSPITAL MEDICINE

Guiding Principles for Pediatric Hospital Medicine Programs, 9/13

Medical Staff Appointment and Delineation of Pediatric Privileges in Hospitals (Clinical Report) (joint with Committee on Hospital Care), 3/12

Physicians' Roles in Coordinating Care of Hospitalized Children (Clinical Report) (joint with Committee on Hospital Care), 9/10

SECTION ON INTEGRATED MEDICINE

Physician Health and Wellness (Clinical Report) (joint with Committee on Practice and Ambulatory Medicine), 9/14

SECTION ON INTERNATIONAL CHILD HEALTH

Increasing Antiretroviral Drug Access for Children With HIV Infection (joint with Committee on Pediatric AIDS), 4/07, reaffirmed 4/10

SECTION ON MEDICAL STUDENTS, RESIDENTS, AND FELLOWSHIP TRAINEES

Parental Leave for Residents and Pediatric Training Programs (joint with Committee on Early Childhood), 1/13

SECTION ON NEUROLOGICAL SURGERY

Prevention and Management of Positional Skull Deformities in Infants (Clinical Report) (joint with Committee on Practice and Ambulatory Medicine), 11/11

SECTION ON NEUROLOGY

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations (Clinical Report) (joint with Section on Critical Care, Society of Critical Care Medicine, and Child Neurology Society), 8/11

SECTION ON OPHTHALMOLOGY

Eye Examination in Infants, Children, and Young Adults by Pediatricians (joint with Committee on Practice and Ambulatory Medicine, American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology), 4/03, reaffirmed 5/07

The Eye Examination in the Evaluation of Child Abuse (Clinical Report) (joint with Committee on Child Abuse and Neglect), 7/10

Instrument-Based Pediatric Vision Screening Policy Statement (joint with Committee on Practice and Ambulatory Medicine, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 10/12

Learning Disabilities, Dyslexia, and Vision (joint with Council on Children With Disabilities, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 7/09, reaffirmed 7/14

Learning Disabilities, Dyslexia, and Vision (Technical Report) (joint with Council on Children With Disabilities, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 3/11

Ophthalmologic Examinations in Children With Juvenile Rheumatoid Arthritis (Clinical Report) (joint with Section on Rheumatology), 5/06, reaffirmed 10/12

Red Reflex Examination in Neonates, Infants, and Children (joint with American Association for Pediatric Ophthalmology and Strabismus, American Academy of Ophthalmology, and American Association of Certified Orthoptists), 12/08

Screening Examination of Premature Infants for Retinopathy of Prematurity (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists), 12/12

Screening for Retinopathy in the Pediatric Patient With Type 1 Diabetes Mellitus (Clinical Report) (joint with Section on Endocrinology and American Association for Pediatric Ophthalmology and Strabismus), 7/05, reaffirmed 1/09, 7/14

SECTION ON ORAL HEALTH (FORMERLY SECTION ON PEDIATRIC DENTISTRY AND SECTION ON PEDIATRIC DENTISTRY AND ORAL HEALTH)

Fluoride Use in Caries Prevention in the Primary Care Setting, 8/14

Maintaining and Improving the Oral Health of Young Children, 11/14

Management of Dental Trauma in a Primary Care Setting (Clinical Report), 1/14

Oral Health Care for Children With Developmental Disabilities (Clinical Report) (joint with Council on Children With Disabilities), 2/13

Oral Health Risk Assessment Timing and Establishment of the Dental Home, 5/03, reaffirmed 5/09

Preventive Oral Health Intervention for Pediatricians, 12/08

SECTION ON ORTHOPAEDICS

Anterior Cruciate Ligament Injuries: Diagnosis, Treatment, and Prevention (Clinical Report) (joint with Council on Sports Medicine), 4/14

Evaluating Children With Fractures for Child Physical Abuse (Clinical Report), (joint with Committee on Child Abuse and Neglect; Section on Radiology; Section on Endocrinology; and Society for Pediatric Radiology), 1/14

Management of Pediatric Trauma (joint with Committee on Pediatric Emergency Medicine, Section on Critical Care, Section on Surgery, Section on Transport Medicine, and Pediatric Orthopaedic Society of North America), 4/08, reaffirmed 4/13

SECTION ON OTOLARYNGOLOGY—HEAD & NECK SURGERY

Cochlear Implants in Children: Surgical Site Infections and Prevention and Treatment of Acute Otitis Media and Meningitis (joint with Committee on Infectious Diseases), 7/10

Follow-up Management of Children With Tympanostomy Tubes, 2/02

Hearing Assessment in Infants and Children: Recommendations Beyond Neonatal Screening (Clinical Report) (joint with Committee on Practice and Ambulatory Medicine), 9/09

SECTION ON RADIOLOGY

Diagnostic Imaging of Child Abuse, 4/09

Evaluating Children With Fractures for Child Physical Abuse (Clinical Report), (joint with Committee on Child Abuse and Neglect; Section on Endocrinology; Section on Orthopaedics; and Society for Pediatric Radiology), 1/14

Radiation Risk to Children From Computed Tomography (Clinical Report), 9/07

SECTION ON RHEUMATOLOGY

Ophthalmologic Examinations in Children With Juvenile Rheumatoid Arthritis (Clinical Report) (joint with Section on Ophthalmology), 5/06, reaffirmed 10/12

SECTION ON SURGERY

Assessment and Management of Inguinal Hernia in Infants (Clinical Report) (joint with Committee on Fetus and Newborn), 9/12

Do-Not-Resuscitate Orders for Pediatric Patients Who Require Anesthesia and Surgery (Clinical Report) (joint with Section on Anesthesia and Pain Medicine and Committee on Bioethics), 12/04, reaffirmed 1/09, 10/12

Management of Pediatric Trauma (joint with Section on Orthopaedics, Committee on Pediatric Emergency Medicine, Section on Critical Care, Section on Transport Medicine, and Pediatric Orthopaedic Society of North America), 4/08, reaffirmed 4/13

Pediatric Organ Donation and Transplantation (joint with Committee on Hospital Care and Section on Critical Care), 3/10, reaffirmed 3/14

Postdischarge Follow-up of Infants With Congenital Diaphragmatic Hernia (Clinical Report) (joint with Committee on Fetus and Newborn), 3/08, reaffirmed 5/11

Preservation of Fertility in Pediatric and Adolescent Patients With Cancer (Technical Report) (joint with Committee on Bioethics and Section on Hematology/Oncology), 5/08, reaffirmed 2/12

Prevention and Management of Pain in the Neonate: An Update (joint with Committee on Fetus and Newborn and Canadian Paediatric Society), 11/06, reaffirmed 5/10

SECTION ON TELEHEALTH CARE (FORMERLY SECTION ON TELEPHONE CARE)

Payment for Telephone Care (joint with Committee on Child Health Financing), 10/06

SECTION ON TRANSPORT MEDICINE

Management of Pediatric Trauma (joint with Section on Orthopaedics, Committee on Pediatric Emergency Medicine, Section on Critical Care, Section on Surgery, and Pediatric Orthopaedic Society of North America), 4/08, reaffirmed 4/13

SECTION ON UNIFORMED SERVICES

Health and Mental Health Needs of Children in US Military Families (Clinical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health), 5/13

STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT

ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents (Clinical Practice Guideline) (joint with Subcommittee on Attention-Deficit/Hyperactivity Disorder), 10/11

Chronic Abdominal Pain in Children (Clinical Report) (joint with Subcommittee on Chronic Abdominal Pain and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition), 3/05

Chronic Abdominal Pain in Children (Technical Report) (joint with Subcommittee on Chronic Abdominal Pain and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition), 3/05

Classifying Recommendations for Clinical Practice Guidelines, 9/04

Developmental Dysplasia of the Hip Practice Guideline (Technical Report), 4/00

Diagnosis and Management of Acute Otitis Media (Clinical Practice Guideline) (joint with American Academy of Family Physicians), 5/04

Diagnosis and Management of an Initial UTI in Febrile Infants and Young Children (Technical Report) (joint with Subcommittee on Urinary Tract Infection), 8/11

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (Clinical Practice Guideline) (joint with Subcommittee on Obstructive Sleep Apnea Syndrome), 8/12

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (Technical Report) (joint with Subcommittee on Obstructive Sleep Apnea Syndrome), 8/12

Early Detection of Developmental Dysplasia of the Hip (Clinical Practice Guideline), 4/00

An Evidence-Based Review of Important Issues Concerning Neonatal Hyperbilirubinemia (Technical Report) (joint with Subcommittee on Hyperbilirubinemia), 7/04

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures (Clinical Practice Guideline) (joint with Subcommittee on Febrile Seizures), 6/08

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation (Clinical Practice Guideline) (joint with Subcommittee on Hyperbilirubinemia), 7/04

Management of Sinusitis (Clinical Practice Guideline), 9/01

Otitis Media With Effusion (Clinical Practice Guideline) (joint with Subcommittee on Otitis Media With Effusion), 5/04

Principles for the Development and Use of Quality Measures (joint with Committee on Practice and Ambulatory Medicine), 2/08

Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care (joint with Committee on Hospital Care), 5/11

Toward Transparent Clinical Policies, 3/08, reaffirmed 2/14

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months (Clinical Practice Guideline) (joint with Subcommittee on Urinary Tract Infection), 8/11

SUBCOMMITTEE ON ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 10/11

SUBCOMMITTEE ON CHRONIC ABDOMINAL PAIN

Chronic Abdominal Pain in Children (Clinical Report) (joint with Steering Committee on Quality Improvement and Management and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition), 3/05

Chronic Abdominal Pain in Children (Technical Report) (joint with Steering Committee on Quality Improvement and Management and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition), 3/05

SUBCOMMITTEE ON FEBRILE SEIZURES

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 6/08

Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure (Clinical Practice Guideline), 2/11

SUBCOMMITTEE ON HYPERBILIRUBINEMIA

An Evidence-Based Review of Important Issues Concerning Neonatal Hyperbilirubinemia (Technical Report) (joint with Steering Committee on Quality Improvement and Management), 7/04

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 7/04

SUBCOMMITTEE ON OBSTRUCTIVE SLEEP APNEA SYNDROME

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 8/12

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (Technical Report) (joint with Steering Committee on Quality Improvement and Management), 8/12

SUBCOMMITTEE ON OTITIS MEDIA WITH EFFUSION

Otitis Media With Effusion (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 5/04

SUBCOMMITTEE ON URINARY TRACT INFECTION

Diagnosis and Management of an Initial UTI in Febrile Infants and Young Children (Technical Report) (joint with Steering Committee on Quality Improvement and Management), 8/11

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months (Clinical Practice Guideline) (joint with Steering Committee on Quality Improvement and Management), 8/11

SURGICAL ADVISORY PANEL

Referral to Pediatric Surgical Specialists, 1/14

TASK FORCE ON CIRCUMCISION

Circumcision Policy Statement, 8/12

Male Circumcision (Technical Report), 8/12

TASK FORCE ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

The Use of Complementary and Alternative Medicine in Pediatrics (Clinical Report) (joint with Provisional Section on Complementary, Holistic, and Integrative Medicine), 12/08, reaffirmed 10/12, 1/13

TASK FORCE ON GRADUATE MEDICAL EDUCATION REFORM

Graduate Medical Education and Pediatric Workforce Issues and Principles, 6/94

TASK FORCE ON MENTAL HEALTH

The Future of Pediatrics: Mental Health Competencies for Pediatric Primary Care (joint with Committee on Psychosocial Aspects of Child and Family Health), 6/09, reaffirmed 8/13

TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

The Changing Concept of Sudden Infant Death Syndrome: Diagnostic Coding Shifts, Controversies Regarding the Sleeping Environment, and New Variables to Consider in Reducing Risk, 11/05, reaffirmed 5/08

SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment, 10/11

SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment (Technical Report), 10/11

TASK FORCE ON TERRORISM

The Pediatrician and Disaster Preparedness (joint with Committee on Pediatric Emergency Medicine and Committee on Medical Liability), 2/06, reaffirmed 6/09, 9/13

Psychosocial Implications of Disaster or Terrorism on Children: A Guide for the Pediatrician (Clinical Report) (joint with Committee on Psychosocial Aspects of Child and Family Health), 9/05

WORK GROUP ON SEDATION

Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update (Clinical Report) (joint with American Academy of Pediatric Dentistry), 12/06, reaffirmed 3/11

WORKING GROUP ON SLEEPINESS IN ADOLESCENTS/YOUNG ADULTS

Excessive Sleepiness in Adolescents and Young Adults: Causes, Consequences, and Treatment Strategies (Technical Report) (joint with Committee on Adolescence), 6/05

JOINT STATEMENTS

Joint Statement of the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry

Psychological Maltreatment (Clinical Report), 7/12

Joint Statement of the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, and the National Center for Child Traumatic Stress

Behavioral and Emotional Consequences of Child Abuse (Clinical Report), 9/08, reaffirmed 8/12

Joint Statement of the American Academy of Pediatrics and the American Academy of Family Physicians

Diagnosis and Management of Acute Otitis Media (Clinical Practice Guideline), 5/04

Joint Statement of the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians

Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home (Clinical Report), 7/11

Joint Statement of the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians-American Society of Internal Medicine

A Consensus Statement on Health Care Transitions for Young Adults With Special Health Care Needs, 12/02

Joint Statement of the American Academy of Pediatrics and the American Academy of Ophthalmology

Protective Eyewear for Young Athletes, 3/04, reaffirmed 2/08, 6/11

Joint Statement of the American Academy of Pediatrics, the American Academy of Ophthalmology, the American Association for Pediatric Ophthalmology and Strabismus, and the American Association of Certified Orthoptists

Instrument-Based Pediatric Vision Screening Policy Statement, 10/12

Screening Examination of Premature Infants for Retinopathy of Prematurity, 12/12

Joint Statement of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry

Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update (Clinical Report), 12/06, reaffirmed 3/11

Oral and Dental Aspects of Child Abuse and Neglect (Clinical Report), 12/05, reaffirmed 1/09, 1/14

Joint Statement of the American Academy of Pediatrics, the American Association of Certified Orthoptists, the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology

Eye Examination in Infants, Children, and Young Adults by Pediatricians, 4/03, reaffirmed 5/07

Learning Disabilities, Dyslexia, and Vision, 7/09, reaffirmed 7/14

Learning Disabilities, Dyslexia, and Vision (Technical Report), 3/11

Red Reflex Examination in Neonates, Infants, and Children, 12/08

Joint Statement of the American Academy of Pediatrics and the American Association for Pediatric Ophthalmology and Strabismus

Screening for Retinopathy in the Pediatric Patient With Type 1 Diabetes Mellitus (Clinical Report), 7/05, reaffirmed 1/09, 7/14

Joint Statement of the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association

ACCF/AHA/AAP Recommendations for Training in Pediatric Cardiology, 12/05, reaffirmed 1/09

Joint Statement of the American Academy of Pediatrics and the American College of Emergency Physicians

Emergency Information Forms and Emergency Preparedness for Children With Special Health Care Needs, 3/10, reaffirmed 7/14

Patient- and Family-Centered Care and the Role of the Emergency Physician Providing Care to a Child in the Emergency Department, 11/06, reaffirmed 6/09, 10/11

Pediatric Mental Health Emergencies in the Emergency Medical Services System, 10/06, reaffirmed 6/09, 4/13

Joint Statement of the American Academy of Pediatrics; the American College of Emergency Physicians; the American College of Surgeons Committee on Trauma; Emergency Medical Services for Children; the Emergency Nurses Association; the National Association of EMS Physicians; and the National Association of State EMS Officials

Equipment for Ground Ambulances, 8/14

Joint Statement of the American Academy of Pediatrics, the American College of Emergency Physicians, and the Emergency Nurses Association

Death of a Child in the Emergency Department, 6/14

Death of a Child in the Emergency Department (Technical Report), 6/14

Guidelines for Care of Children in the Emergency Department, 9/09, reaffirmed 4/13

Joint Statement of the American Academy of Pediatrics and the American College of Medical Genetics and Genomics

Ethical and Policy Issues in Genetic Testing and Screening of Children, 2/13

Joint Statement of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists

The Apgar Score, 4/06, reaffirmed 1/09

Human Immunodeficiency Virus Screening, 7/99, reaffirmed 6/02, 5/05, 10/08, 5/12

Immersion in Water During Labor and Delivery (Clinical Report), 3/14

Maternal-Fetal Intervention and Fetal Care Centers (Clinical Report), 7/11

Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign (Clinical Report), 11/06

Joint Statement of the American Academy of Pediatrics, the American College of Surgeons Committee on Trauma, and the National Association of EMS Physicians

Withholding or Termination of Resuscitation in Pediatric Out-of-Hospital Traumatic Cardiopulmonary Arrest, 3/14

Joint Statement of the American Academy of Pediatrics and the American Heart Association

Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP, 8/09

Joint Statement of the American Academy of Pediatrics, the American Thyroid Association, and the Lawson Wilkins Pediatric Endocrine Society

Update of Newborn Screening and Therapy for Congenital Hypothyroidism (Clinical Report), 6/06, reaffirmed 12/11

Joint Statement of the American Academy of Pediatrics and the Canadian Paediatric Society

Boxing Participation by Children and Adolescents, 8/11
Early Childhood Caries in Indigenous Communities, 5/11

Prevention and Management of Pain in the Neonate: An Update, 11/06, reaffirmed 5/10

Joint Statement of the American Academy of Pediatrics and the Child Life Council

Child Life Services, 4/14

Joint Statement of the American Academy of Pediatrics and the Children's Oncology Group

Long-term Follow-up Care for Pediatric Cancer Survivors (Clinical Report), 3/09, reaffirmed 4/13

Joint Statement of the American Academy of Pediatrics and the Institute for Patient- and Family-Centered Care

Patient- and Family-Centered Care and the Pediatrician's Role, 1/12

Joint Statement of the American Academy of Pediatrics and the National Association of Medical Examiners

Distinguishing Sudden Infant Death Syndrome From Child Abuse Fatalities (Clinical Report), 7/06, reaffirmed 4/09, 3/13

Joint Statement of the American Academy of Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

Chronic Abdominal Pain in Children (Clinical Report), 3/05

Chronic Abdominal Pain in Children (Technical Report), 3/05

Joint Statement of the American Academy of Pediatrics and Others

Insurance Coverage of Mental Health and Substance Abuse Services for Children and Adolescents: A Consensus Statement, 10/00

Joint Statement of the American Academy of Pediatrics and the Pediatric Orthopaedic Society of North America

Management of Pediatric Trauma, 4/08, reaffirmed 4/13

Joint Statement of the American Academy of Pediatrics and the Society for Adolescent Health Care

Screening for Nonviral Sexually Transmitted Infections in Adolescents and Young Adults, 6/14

Joint Statement of the American Academy of Pediatrics and the Society for Pediatric Radiology

Evaluating Children With Fractures for Child Physical Abuse (Clinical Report), 1/14

Joint Statement of the American Academy of Pediatrics and the Society of Critical Care Medicine

Admission and Discharge Guidelines for the Pediatric Patient Requiring Intermediate Care (Clinical Report), 5/04, reaffirmed 2/08, 1/13

Guidelines for Developing Admission and Discharge Policies for the Pediatric Intensive Care Unit (Clinical Report), 4/99, reaffirmed 5/05, 2/08, 1/13

Joint Statement of the American Academy of Pediatrics, the Society of Critical Care Medicine, and the Child Neurology Society

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations (Clinical Report), 8/11

Joint Statement of the Federation of Pediatric Organizations

Pediatric Fellowship Training, 7/04

ENDORSED CLINICAL PRACTICE GUIDELINES AND POLICIES

(The AAP endorses and accepts as its policy the following clinical practice guidelines and policies that have been published by other organizations.)

Advisory Committee on Immunization Practices

General Recommendations on Immunization:
Recommendations of the Advisory Committee on Immunization Practices (ACIP), 12/06

Advisory Committee on Immunization Practices and Centers for Disease Control and Prevention

A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, 7/06

Ambulatory Pediatric Association

Report of the National Consensus Conference on Family Presence during Pediatric Cardiopulmonary Resuscitation and Procedures, 9/03

American Academy of Child and Adolescent Psychiatry and Child Welfare League of America

Foster Care Mental Health Values, 2002

Mental Health and Substance Use Screening and Assessment of Children in Foster Care, 2003

American Academy of Emergency Medicine, American Association of Critical Care Nurses, American College of Emergency Physicians, Association of periOperative Registered Nurses, Emergency Department Practice Management Association, Emergencies Nurses Association, and National Association of EMS Physicians

Consensus Statement: Definitions for Consistent Emergency Department Metrics (2/10)

American Academy of Family Physicians, American Academy of Orthopaedic Surgeons, American College of Sports Medicine, American Medical Society for Sports Medicine, American Orthopaedic Society for Sports Medicine, and American Osteopathic Academy of Sports Medicine

Selected Issues for the Adolescent Athlete and the Team Physician: A Consensus Statement, 11/08

American Academy of Neurology and Child Neurology Society

Diagnostic Assessment of the Child With Cerebral Palsy (Clinical Practice Guideline), 3/04

Diagnostic Assessment of the Child With Status Epilepticus (An Evidence-based Review) (Clinical Practice Guideline), 11/06

Evidence Report: Genetic and Metabolic Testing on Children With Global Developmental Delay, 9/11

Evidence-Based Guideline Update: Medical Treatment of Infantile Spasms, 6/12

Neuroimaging of the Neonate (Clinical Practice Guideline), 6/02

Pharmacological Treatment of Migraine Headache in Children and Adolescents (Clinical Practice Guideline), 12/04

Screening and Diagnosis of Autism (Clinical Practice Guideline), 8/00

Treatment of the Child With a First Unprovoked Seizure (Clinical Practice Guideline), 1/03

American Academy of Neurology, Child Neurology Society, and American Epilepsy Society

Evaluating a First Nonfebrile Seizure in Children (Clinical Practice Guideline), 8/00

American College of Cardiology

Appropriate Use Criteria for Initial Transthoracic Echocardiography in Outpatient Pediatric Cardiology, 11/14

American College of Emergency Physicians

Clinical Policy: Evidence-based Approach to Pharmacologic Agents Used in Pediatric Sedation and Analgesia in the Emergency Department (Clinical Practice Guideline), 10/04

American College of Obstetricians and Gynecologists

Neonatal Encephalopathy and Neurologic Outcome, Second Edition, 4/14

Timing of Umbilical Cord Clamping After Birth, 12/12

American College of Rheumatology

Guidelines for Referral of Children and Adolescents to Pediatric Rheumatologists, 6/02, reaffirmed 5/07

American Diabetes Association

Diabetes Care for Emerging Adults: Recommendations for Transition From Pediatric to Adult Diabetes Care Systems, 11/11

Safe at School Campaign Statement of Principles, endorsed 2/06

American Heart Association

Cardiovascular Risk Reduction in High-Risk Pediatric Populations, 12/06

Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Statement for Health Professionals, 12/04

Dietary Recommendations for Children and Adolescents: A Guide for Practitioners, 9/05

Genetic Basis for Congenital Heart Defects: Current Knowledge, 6/07

Importance and Implementation of Training in Cardiopulmonary Resuscitation and Automated External Defibrillation in Schools, 2/11

Long-term Cardiovascular Toxicity in Children, Adolescents, and Young Adults Who Receive Cancer Therapy: Pathophysiology, Course, Monitoring, Management, Prevention, and Research Directions: A Scientific Statement From the American Heart Association, 5/13

Neurodevelopmental Outcomes in Children With Congenital Heart Disease: Evaluation and Management: A Scientific Statement From the American Heart Association, 7/12

Noninherited Risk Factors and Congenital Cardiovascular Defects: Current Knowledge, 6/07

Prevention of Infective Endocarditis: Guidelines From the American Heart Association (Clinical Practice Guideline), 5/07

Prevention of Rheumatic Fever and Diagnosis and Treatment of Acute Streptococcal Pharyngitis, 2/09

Response to Cardiac Arrest and Selected Life-Threatening Medical Emergencies: The Medical Emergency Response Plan for Schools. A Statement for Healthcare Providers, Policymakers, School Administrators, and Community Leaders, 1/04

American Medical Association

Gifts to Physicians From Industry, 8/01

American Pediatric Surgical Association

Best Practice for Infant Surgery: A Position Statement From the American Pediatric Surgical Association, 9/08

American Society for Parenteral and Enteral Nutrition

Defining Pediatric Malnutrition: A Paradigm Shift

Toward Etiology-Related Definitions, 3/13

American Thoracic Society and Centers for Disease Control and Prevention

(The AAP endorses and accepts as its policy the sections of this statement as they relate to infants and children.)

Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, 4/00

American Urological Association

Report on the Management of Primary Vesicoureteral Reflux in Children (Clinical Practice Guideline), 5/97

Canadian Paediatric Society

Skiing and Snowboarding Injury Prevention, 1/12

Centers for Disease Control and Prevention

Guidelines for Field Triage of Injured Patients, 1/12

Managing Acute Gastroenteritis Among Children: Oral Rehydration, Maintenance, and Nutritional Therapy (Clinical Practice Guideline), 11/03

Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 3/13

Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines from CDC, 2010 (Clinical Practice Guideline), 11/10

Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States (Clinical Practice Guideline), 8/01

Update on Japanese Encephalitis Vaccine for Children—United States, May 2011, 8/11

Centers for Disease Control and Prevention, Infectious Diseases Society of America, and American Society of Blood and Marrow Transplantation

Guidelines for Preventing Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients (Clinical Practice Guideline), 10/00

Emergency Nurses Association

Weighing Pediatric Patients in Kilograms, 3/12

The Endocrine Society

Congenital Adrenal Hyperplasia Due to Steroid 21-hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline (Clinical Practice Guideline), 9/10

Family Violence Prevention Fund

Identifying and Responding to Domestic Violence: Consensus Recommendations for Child and Adolescent Health, 9/02

Guidelines for Adolescent Depression in Primary Care Steering Group

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): I. Identification, Assessment, and Initial Management (Clinical Practice Guideline), 11/07

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): II. Treatment and Ongoing Management (Clinical Practice Guideline), 11/07

Infectious Diseases Society of America

2013 Infectious Diseases Society of America Clinical Practice Guidelines for the Immunization of the Immunocompromised Host, (Clinical Practice Guideline) 12/13

Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant *Staphylococcus aureus* Infections in Adults and Children (Clinical Practice Guideline), 2/11

Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America (Clinical Practice Guideline), 4/09

Institute of Medicine

Dietary Reference Intakes for Calcium and Vitamin D, 2011

International Consensus Conference on Intersex (Lawson Wilkins Pediatric Endocrine Society and the European Society for Paediatric Endocrinology)

Consensus Statement on Management of Intersex Disorders, 8/06

Joint Committee on Infant Hearing

Supplement to the JCIH 2007 Position Statement: Principles and Guidelines for Early Intervention After Confirmation That a Child Is Deaf or Hard of Hearing, 3/13

National Adoption Center

National Adoption Center: Open Records, 6/00

National Association of Neonatal Nurses

Advanced Practice Registered Nurse: Role, Preparation, and Scope of Practice, 1/14

The Management of Hypotension in the Very-Low-Birth-Weight Infant: Guideline for Practice, 2011

National Association of School Nurses

Emergency Equipment and Supplies in the School Setting, 1/12

National Athletic Trainers' Association

Appropriate Medical Care for the Secondary School-Age Athlete Communication, 2004

Lightning Safety for Athletics and Recreation, 12/00

National Athletic Trainers' Association, National Interscholastic Athletic Administrators Association, College Athletic Trainers' Society, National Federation of State High School Associations, American College Health Association, American Orthopaedic Society for Sports Medicine, National Collegiate Athletic Association, American Medical Society for Sports Medicine, National Association of Collegiate Directors of Athletics, and National Association of Intercollegiate Athletics

Inter-Association Consensus Statement on Best Practices for Sports Medicine Management for Secondary Schools and Colleges, 7/13

National Consensus Project for Quality Palliative Care
Clinical Practice Guidelines for Quality Palliative Care, Third Edition, 2013

National Diabetes Education Program

Helping the Student with Diabetes Succeed: A Guide for School Personnel, 6/03

National Heart, Lung and Blood Institute

Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report, 3/12

National Institute of Allergy and Infectious Diseases

Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel (Clinical Practice Guideline), 12/10

National Vaccine Advisory Committee

Enhancing the Work of the HHS National Vaccine Program in Global Immunizations, 9/13

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

Guideline for the Evaluation of Cholestatic Jaundice in Infants (Clinical Practice Guideline), 8/04

Guidelines for Evaluation and Treatment of Gastroesophageal Reflux in Infants and Children (Clinical Practice Guideline), 2001

Helicobacter pylori Infection in Children: Recommendations for Diagnosis and Treatment (Clinical Practice Guideline), 11/00

Pediatric Infectious Diseases Society and Infectious Diseases Society of America

The Management of Community-Acquired Pneumonia (CAP) in Infants and Children Older Than 3 Months of Age (Clinical Practice Guideline), 10/11

Pediatric Orthopaedic Society of North America, American Academy of Orthopaedic Surgeons, and Scoliosis Research Society

Screening for Idiopathic Scoliosis in Adolescents, 1/08

Renal Physicians Association

Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis, 2nd Edition (Clinical Practice Guideline), 10/10

Society for Academic Emergency Medicine

Pediatric Care in the Emergency Department, 11/03

Society for Adolescent Medicine

Executing Juvenile Offenders: A Fundamental Failure of Society, 10/04

Expedited Partner Therapy for Adolescents Diagnosed With Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine, 9/09

Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse, 11/04

Society for Research in Child Development

Multilingual Children: Beyond Myths and Toward Best Practices, 2013

Society of Critical Care Medicine, Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Surgical Infection Society, American College of Chest Physicians, American Thoracic Society, American Society of Critical Care Anesthesiologists, Association for Professionals in Infection Control and Epidemiology, Infusion Nurses Society, Oncology Nursing Society, Society of Cardiovascular and Interventional Radiology, American Academy of Pediatrics, and Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention

Guidelines for the Prevention of Intravascular Catheter-Related Infections (Clinical Practice Guideline), 11/02

US Department of Health and Human Services

Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children (Clinical Practice Guideline), 11/13
Treating Tobacco Use and Dependence: 2008 Update (Clinical Practice Guideline), 5/08

World Health Organization

(The AAP endorses the recommendation pertaining to the use of thimerosal in vaccines.)

Meeting of the Strategic Advisory Group of Experts on Immunizations, April 2012—Conclusions and Recommendations, 5/12

AFFIRMATION OF VALUE CLINICAL PRACTICE GUIDELINES AND POLICIES

(These guidelines are not endorsed as policy of the American Academy of Pediatrics [AAP]. Documents that lack a clear description of the process for identifying, assessing, and incorporating research evidence are not eligible for AAP endorsement as practice guidelines. However, such documents may be of educational value to members of the AAP.)

American Society of Anesthesiologists

Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea (Clinical Practice Guideline), 5/06

National Environmental Education Foundation

Environmental Management of Pediatric Asthma: Guidelines for Health Care Providers (Clinical Practice Guideline), 8/05

National Hospice and Palliative Care Organization

Standards of Practice for Pediatric Palliative Care and Hospice (Clinical Practice Guideline), 2/09

Turner Syndrome Consensus Study Group

Care of Girls and Women With Turner Syndrome: A Guideline of the Turner Syndrome Study Group (Clinical Practice Guideline), 1/07

APPENDIX 2

PPI: AAP Partnership for Policy Implementation



BACKGROUND

The American Academy of Pediatrics (AAP) develops policies that promote attainment of optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. These documents are valued highly not only by clinicians who provide direct health care to children but by members of other organizations who share similar goals and by parents, payers, and legislators. Unfortunately, AAP policy documents vary widely in terms of how they are written, and some find these documents difficult to implement. Pediatricians who have expertise in medical informatics found AAP policy documents particularly challenging when they tried to convert policy recommendations into items that could be easily programmed into an electronic system. In June 2005, with initial funding support from the federal Maternal and Child Health Bureau, the AAP launched the Partnership for Policy Implementation (PPI), a pilot program to create changes in development of policy statements, clinical reports, technical reports, and clinical practice guidelines—specifically, how they are written. The PPI process is a collaboration between informaticians and subject matter experts that integrates health information technology (HIT) functionalities into AAP policy. The PPI is currently funded by the AAP Child Health Informatics Center (CHIC).

VISION

The vision of the PPI is that all AAP clinical recommendations include clear guidance on how pediatricians can implement those recommendations into their patient care and that AAP clinical guidance can be easily incorporated within electronic health record decision-support systems.

MISSION

The mission of the PPI is to facilitate implementation of AAP recommendations at the point of care by ensuring that AAP documents are written in a practical, action-oriented fashion with unambiguous recommendations.

WHAT IS THE PPI?

The PPI is a network of pediatric informaticians who work with AAP authors and guideline subcommittees throughout the writing process.

Contributions of the PPI to the AAP writing process include disambiguation and specification; development of clear definitions; clearly defined logic; implementation

techniques; action-oriented recommendations, including clinical algorithms; transparency of evidence basis for recommendations; and health information technology (HIT) standard development.

WHAT HAS THE PPI ACCOMPLISHED?

Since inception of the PPI, more than 20 statements have been published using the PPI process, covering a wide variety of child health topics, including child passenger safety (*Pediatrics*. 2011;127:788–793), harm reduction (*Pediatrics*. 2011; 127:1199–1210), type 2 diabetes (*Pediatrics*. 2013; 131:364–382), and bronchiolitis (*Pediatrics*. 2014; 134:e1474–e1502).

One example of how a statement developed using PPI process has gained broader acceptance is the AAP annual influenza statement. Since 2007, the Centers for Disease Control and Prevention have adopted components of the PPI statement (specifically, the clinical algorithm) within its own statement on the same topic. In addition, the Childhood Influenza Immunization Coalition posted an interactive version of the influenza algorithm on its Web site (www.preventchildhoodinfluenza.org/resource/algorithm.swf).

WHAT IS THE PPI DOING NOW?

In addition to creating practical, action-oriented documents that pediatricians can use, the PPI is also working to make it easier for these documents to be incorporated into electronic systems. To date, the PPI has focused its involvement on the statement development process. Involvement of the PPI during the writing process helps to produce a clear, more concise document. As these standards of care become well documented, the PPI can begin to focus on building or mapping pediatric vocabulary; once solidified, this vocabulary can be built into electronic health record (EHR) systems. The standards of care can also be matched to various logical and functional HIT standards that already exist today. Through this work, the PPI improves AAP policy documents by providing specific guidance to pediatricians at the point of care, helping ensure that EHRs are designed to assist pediatricians in providing optimal care for children.

For more information about the PPI, please visit its Web site (<http://www2.aap.org/informatics/PPI.html>) or contact Lisa Krams (lkrams@aap.org or 847/434-7663).

APPENDIX 3

American Academy of Pediatrics Acronyms

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AMERICAN ACADEMY OF PEDIATRICS

Acronyms

AACAP	American Academy of Child and Adolescent Psychiatry	ACOP	American College of Osteopathic Pediatricians
AAFP	American Academy of Family Physicians	ACP	American College of Physicians
AAMC	Association of American Medical Colleges	ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
AAOS	American Academy of Orthopaedic Surgeons	AG-M	Action Group—Multidisciplinary (Section Forum)
AAP	American Academy of Pediatrics	AG-M1	Action Group—Medical 1 (Section Forum)
AAPD	American Academy of Pediatric Dentistry	AG-M2	Action Group—Medical 2 (Section Forum)
ABM	Academy of Breastfeeding Medicine	AG-S	Action Group—Surgical (Section Forum)
ABMS	American Board of Medical Specialties	AHA	American Heart Association
ABP	American Board of Pediatrics	AHA	American Hospital Association
ACBOCCSA	Advisory Committee to the Board on Community, Chapter, and State Affairs	AHRQ	Agency for Healthcare Research and Quality
ACBOCSP	Advisory Committee to the Board on Community and Specialty Pediatrics	ALF	Annual Leadership Forum
ACBOE	Advisory Committee to the Board on Education	AMA	American Medical Association
ACBOF	Advisory Committee to the Board on Finance	AMCHP	Association of Maternal and Child Health Programs
ACBOFA	Advisory Committee to the Board on Federal Affairs	AMSA	American Medical Student Association
ACBOGCH	Advisory Committee to the Board on Global Child Health	AMSPDC	Association of Medical School Pediatric Department Chairs
ACBOIT	Advisory Committee to the Board on Information Technology	AMWA	American Medical Women's Association
ACBOM	Advisory Committee to the Board on Membership	APA	Academic Pediatric Association
ACBOMS	Advisory Committee to the Board on Marketing and Sales	APHA	American Public Health Association
ACBOP	Advisory Committee to the Board on Practice	APLS	Advanced Pediatric Life Support
ACBOPUB	Advisory Committee to the Board on Publications	APPD	Association of Pediatric Program Directors
ACBOR	Advisory Committee to the Board on Research	APQ	Alliance for Pediatric Quality
ACBOSP	Advisory Committee to the Board on Strategic Planning	APS	American Pediatric Society
ACBOSP _e	Advisory Committee to the Board on Specialty Pediatrics	AQA	Ambulatory Care Quality Alliance
ACCME	Accreditation Council for Continuing Medical Education	ASHG	American Society of Human Genetics
ACEP	American College of Emergency Physicians	ASTM	American Society of Testing and Materials
ACGME	Accreditation Council for Graduate Medical Education	BHP	Bureau of Health Professions
ACIP	Advisory Committee on Immunization Practices	BIA	Bureau of Indian Affairs
ACMG	American College of Medical Genetics	BLAST	Babysitter Lessons and Safety Training
ACO	Accountable Care Organization	BOD	Board of Directors
ACOG	American Congress of Obstetricians and Gynecologists	BPC	Breastfeeding Promotion Consortium
		CAG	Corporate Advisory Group
		CAMLWG	Children, Adolescents, and Media Leadership Workgroup
		CAP	College of American Pathologists
		CAQI	Chapter Alliance for Quality Improvement
		CATCH	Community Access to Child Health
		CDC	Centers for Disease Control and Prevention
		CESP	Confederation of European Specialty Pediatrics
		CFMC	Chapter Forum Management Committee
		CFT	Cross Functional Team

CHA	Children's Hospital Association	COSH	Council on School Health
CHIP	Children Health Insurance Program	COSMF	Council on Sports Medicine and Fitness
CMC	Council Management Committee	CPS	Canadian Paediatric Society
CME	Continuing Medical Education	CPTI	Community Pediatrics Training Initiative
CMS	Centers for Medicare & Medicaid Services	CQN	Chapter Quality Network
CMSS	Council of Medical Specialty Societies	CSHCN	Children With Special Health Care Needs
CnF	Council Forum	DHHS	Department of Health and Human Services
COA	Committee on Adolescence	DOD	Department of Defense
COB	Committee on Bioethics	DVC	District Vice Chairperson
COCAN	Committee on Child Abuse and Neglect	EBCDLWG	Early Brain and Child Development Leadership Workgroup
COCHF	Committee on Child Health Financing	EC	Executive Committee
COCIT	Council on Clinical Information Technology	ELWG	Epigenetics Leadership Workgroup
COCM	Council on Communications and Media	EMSC	Emergency Medical Services for Children
COCME	Committee on Continuing Medical Education	EPA	Environmental Protection Agency
COCN	Committee on Coding and Nomenclature	EQIPP	Education in Quality Improvement for Pediatric Practice
COCOP	Council on Community Pediatrics	eTACC	Electronic Translation of Academy Clinical Content
COCWD	Council on Children With Disabilities	FCF	Friends of Children Fund
COD	Committee on Drugs	FDA	Food and Drug Administration
CODe	Committee on Development	FERPA II	Family Educational Rights & Privacy Act
COEC	Council on Early Childhood	FOPE II	Future of Pediatric Education II Project
COEH	Council on Environmental Health	FOPO	Federation of Pediatric Organizations
CoF	Committee Forum	FTC	Federal Trade Commission
COFCAKC	Council on Foster Care, Adoption, and Kinship Care	GME	Graduate Medical Education
COFGA	Committee on Federal Government Affairs	HAAC	Historical Archives Advisory Committee
CoFMC	Committee Forum Management Committee	HBB	Helping Babies Breathe
COFN	Committee on Fetus and Newborn	HCCA	Healthy Child Care America
COG	Committee on Genetics	HEDIS	Health Plan Employer Data and Information Set
COGME	Council on Graduate Medical Education (DHHS/HRSA)	HHS	Health and Human Services
COHC	Committee on Hospital Care	HIPAA	Health Insurance Portability and Accountability Act of 1996
COID	Committee on Infectious Diseases	HMO	Health Maintenance Organization
COIVPP	Committee on Injury, Violence, and Poison Prevention	HQA	Hospital Quality Alliance
COM	Committee on Membership	HRSA	Health Resources and Services Administration
COMLRM	Committee on Medical Liability and Risk Management	HTC	Helping the Children
COMSEP	Council on Medical Student Education in Pediatrics (AMSPDC)	HTPCP	Healthy Tomorrows Partnership for Children Program
CON	Committee on Nutrition	IHS	Indian Health Service
CONACH	Committee on Native American Child Health	IMG	International Medical Graduate Institute of Medicine
COPA	Committee on Pediatric AIDS	IOM	Institute of Medicine
COPACFH	Committee on Psychosocial Aspects of Child and Family Health	IPA	International Pediatric Association
COPAM	Committee on Practice and Ambulatory Medicine	IPC	International Pediatric Congress
COPE	Committee on Pediatric Education	IRB	Institutional Review Board
COPEM	Committee on Pediatric Emergency Medicine	LLLI	La Leche League International
COPR	Committee on Pediatric Research	LWG	Leadership Workgroup
COPW	Committee on Pediatric Workforce	MCAN	Merck Childhood Asthma Network
COQIPS	Council on Quality Improvement and Patient Safety	MCH	Maternal and Child Health
CORS	Committee on Residency Scholarships	MCHB	Maternal and Child Health Bureau
COSA	Committee on Substance Abuse	MCN	Migrant Clinicians Network
COSGA	Committee on State Government Affairs	MHICSN-PAC	Medical Home Initiatives for Children With Special Needs Project Advisory Committee
		MHLWG	Mental Health Leadership Work Group
		MRT	Media Resource Team
		NACHC	National Association of Community Health Centers

NAEMSP	National Association of Emergency Medical Physicians	PEPP	Pediatric Education for Prehospital Professionals
NAEPP	National Asthma Education and Prevention Program	PIR	<i>Pediatrics in Review</i>
NAPNAP	National Association of Pediatric Nurse Practitioners	PLA	Pediatric Leadership Alliance
NASPGHAN	North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition	PMO	<i>Practice Management Online</i>
NAWD	National Association of WIC Directors	PPAAC	Private Payer Advocacy Advisory Committee (COCHF Subcommittee)
NBME	National Board of Medical Examiners	PPAC	Past President's Advisory Committee
NcBDDD	National Center on Birth Defects and Developmental Disabilities	PPC-PCMH	Physician Practice Connections—Patient-Centered Medical Home (NCQA)
NCE	National Conference & Exhibition	PPI	Partnership for Policy Implementation
NCEPG	National Conference & Exhibition Planning Group	PREP	Pediatric Review and Education Program
NCQA	National Committee for Quality Assurance	PROS	Pediatric Research in Office Settings
NHLBI	National Heart, Lung, and Blood Institute	PSOIMG	Provisional Section on International Medical Graduates
NHMA	National Hispanic Medical Association	PSOLGBTHW	Provisional Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness
NHTSA	National Highway Traffic Safety Administration	PSOTCo	Provisional Section on Tobacco Control
NIAAA	National Institute on Alcohol Abuse and Alcoholism	PUPVS	Project Universal Preschool Vision Screening
NICHD	National Institute of Child Health and Human Development	QA	Quality Assurance
NICHQ	National Initiative for Children's Healthcare Quality	QI	Quality Improvement
NIDA	National Institute on Drug Abuse	QuIN	Quality Improvement Innovation Network
NIH	National Institutes of Health	RBPE	Resource-Based Practice Expense
NIMH	National Institute of Mental Health	RBRVS	Resource-Based Relative Value Scale
NMA	National Medical Association	RCE	Richmond Center of Excellence
NNC	National Nominating Committee	RRC	Residency Review Committee (ACGME)
NQF	National Quality Forum	RUC	AMA/Specialty Society Relative Value Scale Update Committee
NRHA	National Rural Health Association	RVU	Relative Value Unit
NRMP	National Resident Matching Program	SAM	Society for Adolescent Medicine
NRP	Neonatal Resuscitation Program	SAMHSA	Substance Abuse and Mental Health Services Administration
NSC	National Safety Council	SCHIP	State Children's Health Insurance Program
NVAC	National Vaccine Advisory Committee	SDBP	Society for Developmental and Behavioral Pediatrics
ODPH	Office of Disease Prevention and Health Promotion	SF	Section Forum
OED	Office of the Executive Director	SFMC	Section Forum Management Committee
OHISC	Oral Health Initiative Steering Committee	SOA	Section on Anesthesiology and Pain Medicine
OLWG	Obesity Leadership Workgroup	SOAC	Subcommittee on Access to Care
P4P	Pay for Performance	SOAH	Section on Adolescent Health
PAC	Project Advisory Committee	SOAI	Section on Allergy and Immunology
PAHO	Pan American Health Organization	SOAPM	Section on Administration and Practice Management
PALS	Pediatric Advanced Life Support	SOATT	Section on Advances in Therapeutics and Technology
PAS	Pediatric Academic Societies	SOB	Section on Bioethics
PCO	<i>Pediatric Care Online™</i>	SOBr	Section on Breastfeeding
PCOC	Primary Care Organizations Consortium	SOCAN	Section on Child Abuse and Neglect
PCPCC	Patient-Centered Primary Care Collaborative	SOCC	Section on Critical Care
PCPI	Physician Consortium on Performance Improvement	SOCCS	Section on Cardiology and Cardiac Surgery
PEAC	Practice Expense Advisory Committee	SOCPT	Section on Clinical Pharmacology and Therapeutics
PECOS	Pediatric Education in Community and Office Settings	SOD	Section on Dermatology
PECS	Pediatric Education in Community Settings	SODBP	Section on Developmental and Behavioral Pediatrics
		SOEM	Section on Emergency Medicine

SOEn	Section on Endocrinology	SOPPe	Section on Perinatal Pediatrics
SOEp	Section on Epidemiology	SOPPSM	Section on Pediatric Pulmonology and Sleep Medicine
SOGBD	Section on Genetics and Birth Defects	SOPS	Section on Plastic Surgery
SOGHN	Section on Gastroenterology, Hepatology, and Nutrition	SORa	Section on Radiology
SOGN	Section on Gastroenterology, Herpetology, and Nutrition	SORh	Section on Rheumatology
SOHC	Section on Home Care	SOSM	Section on Senior Members
SOHM	Section on Hospital Medicine	SOSu	Section on Surgery
SOHO	Section on Hematology/Oncology	SOTC	Section on Telehealth Care
SOHPM	Section on Hospice and Palliative Medicine	SOTM	Section on Transport Medicine
SOICH	Section on International Child Health	SOU	Section on Urology
SOID	Section on Infectious Diseases	SOUS	Section on Uniformed Services
SOIM	Section on Integrative Medicine	SOYP	Section on Young Physicians
SOIMP	Section on Internal Medicine/Pediatrics	SPR	Society for Pediatric Research
SOMP	Section on Medicine-Pediatrics	SPWG	Strategic Planning Work Group
SOMSRFT	Section on Medical Students, Residents, and Fellowship Trainees	TA	Technical Assistance
SONp	Section on Nephrology	TA	Technology Assessment
SONS	Section on Neurological Surgery	TFOA	Task Force on Access (also known as Task Force on Health Insurance Coverage and Access to Care)
SONu	Section on Neurology	TFOC	Task Force on Circumcision
SOOb	Section on Obesity	TIPP	The Injury Prevention Program
SOOH	Section on Oral Health	TJC	The Joint Commission
SOOHNS	Section on Otolaryngology/Head & Neck Surgery	UNICEF	United Nations Children's Fund
SOOp	Section on Ophthalmology	UNOS	United Network for Organ Sharing
SOOPe	Section on Osteopathic Pediatricians	USDA	US Department of Agriculture
SOOr	Section on Orthopaedics	WHO	World Health Organization
		WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

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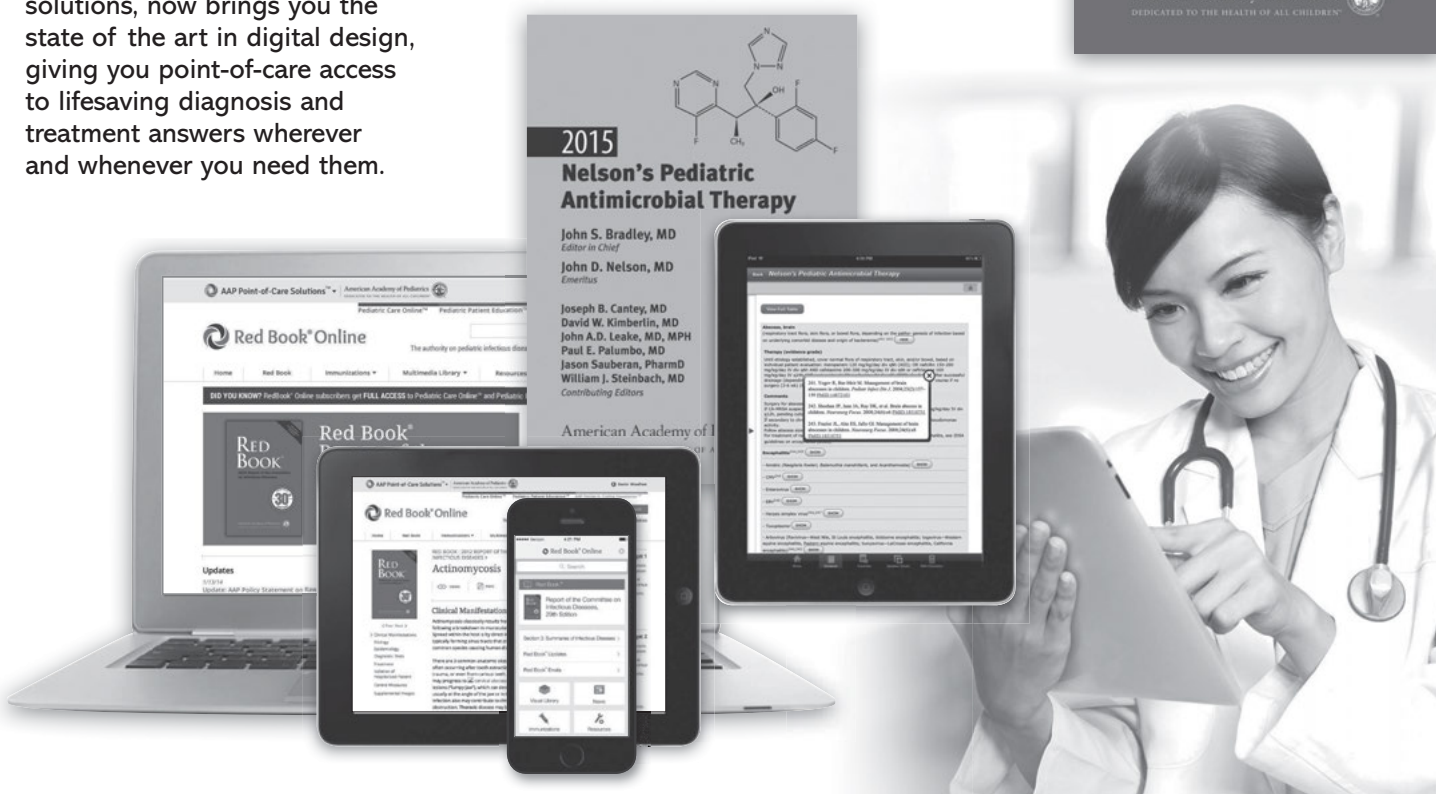
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| Section 3: | Affirmation of Value Clinical Practice Guidelines |
| Section 4: | 2014 Policies From the American Academy of Pediatrics |
| Section 5: | Current Policies From the American Academy of Pediatrics |
| Section 6: | Endorsed Policies |
| Appendix 1: | Policies by Committee |
| Appendix 2: | PPI: AAP Partnership for Policy Implementation |
| Appendix 3: | American Academy of Pediatrics Acronyms |

- Nonfebrile seizures
- Otitis media
- Radiology
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